

EXHIBIT C

Vladimir Iakovlev, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC.,

Master File No.

PELVIC REPAIR SYSTEM PRODUCTS

2:12-MD-02327

LIABILITY LITIGATION

MDL 2327

THIS DOCUMENT RELATES TO CASE

CONSOLIDATION:

Terreski Mullins, et al., v.

Ethicon, Inc., et al.

Case No. 2:12-CV-02952

DEPOSITION OF
VLADIMIR IAKOVLEV, M.D.

* * * *

HIGHLY CONFIDENTIAL PORTION

* * * *

September 11, 2015

9:00 a.m. - 5:05 p.m.

Vladimir Iakovlev, M.D.

| Page 2 | Page 4 |
|--|---|
| <p>1 Deposition of VLADIMIR IAKOVLEV, M.D.,</p> <p>2 a witness herein, called for examination by counsel</p> <p>3 for the Defense, in the above-mentioned matter, the</p> <p>4 witness having been affirmed, taken at the law</p> <p>5 offices of Siskinds LLP, 100 Lombard Street,</p> <p>6 Toronto, Ontario, commencing at 9:03 a.m. on</p> <p>7 Friday, September 11, 2015, and the proceedings</p> <p>8 taken down by Stenotype and transcribed by</p> <p>9 JUDITH M. CAPUTO, RPR, CSR, CRR.</p> | <p>1 INDEX</p> <p>2</p> <p>3 WITNESS: VLADIMIR IAKOVLEV</p> <p>4 PAGE</p> <p>5 DIRECT EXAMINATION BY MR. THOMAS.....5</p> <p>6 CROSS-EXAMINATION BY MR. ORENT.....296</p> <p>7 **Highly Confidential Portion noted on page 40**</p> <p>8</p> <p>9</p> <p>10 INDEX OF EXHIBITS</p> <p>11 NUMBER/DESCRIPTION PAGE NO.</p> <p>12 NO. 1: Expert Report of Dr. Iakovlev in the 5</p> <p>13 Mullins consolidated cases.</p> <p>14 NO. 2: Supplemental Expert Report of 5</p> <p>15 Dr. Iakovlev in the Mullins consolidated cases.</p> <p>16 NO. 3: Notice of Deposition of Dr. Iakovlev. 5</p> <p>17 NO. 4: Thumb drive. 5</p> <p>18 NO. 5: Study Entitled, "Safety Considerations 259</p> <p>19 for synthetic sling surgery."</p> <p>20 NO. 6: Article entitled, "Degradation of 271</p> <p>21 polypropylene in vivo: A microscopic analysis</p> <p>22 of meshes explanted from patients."</p> <p>23 Authored by Vladimir Iakovlev, et al.</p> <p>24</p> <p>25 -- NOTE: Exhibit 4 was retained by Mr. Thomas.</p> |
| Page 3 | Page 5 |
| <p>1 APPEARANCES:</p> <p>2</p> <p>3 On Behalf of the Consolidated Plaintiffs:</p> <p>4 JONATHAN ORENT, Esquire</p> <p>5 Motley Rice, LLC</p> <p>6 321 South Main Street, Suite 200</p> <p>7 Providence, Rhode Island 02903</p> <p>8 410.457.7700</p> <p>9 jorent@motleyrice.com</p> <p>10</p> <p>11 On Behalf of the Defendants, Ethicon:</p> <p>12 DAVID B. THOMAS, Esquire</p> <p>13 Thomas, Combs & Spann, PLLC</p> <p>14 300 Summers Street, Suite 1380</p> <p>15 Charleston, West Virginia</p> <p>16 304.414.1807</p> <p>17 dthomas@tcspllc.com</p> <p>18</p> <p>19 M. ANDREW SNOWDEN, Esquire</p> <p>20 Butler Snow, LLP</p> <p>21 The Pinnacle at Symphony Place</p> <p>22 150 3rd Avenue South, Suite 1600</p> <p>23 Nashville, Tennessee 37201</p> <p>24 615.651.6700</p> <p>25 andy.snowden@butlersnow.com</p> | <p>1 EXHIBIT NO. 1: Expert Report of</p> <p>2 Dr. Vladimir Iakovlev in the Mullins</p> <p>3 consolidated cases.</p> <p>4 EXHIBIT NO. 2: Supplemental Expert</p> <p>5 Report of Dr. Vladimir Iakovlev in the</p> <p>6 Mullins consolidated cases.</p> <p>7 EXHIBIT NO. 3: Notice of Deposition of</p> <p>8 Dr. Vladimir Iakovlev.</p> <p>9 EXHIBIT NO. 4: Thumb drive.</p> <p>10</p> <p>11 Whereupon,</p> <p>12 VLADIMIR IAKOVLEV, M.D.,</p> <p>13 called for examination by counsel for Defendant</p> <p>14 and having been affirmed by me, was examined and</p> <p>15 testified as follows:</p> <p>16 DIRECT EXAMINATION BY MR. THOMAS:</p> <p>17 Q. Good morning, Doctor.</p> <p>18 We've met before. My name is David</p> <p>19 Thomas. I'm going to ask you a number of questions</p> <p>20 about your expert witness opinion in the Mullins</p> <p>21 case pending in the MDL in West Virginia; fair</p> <p>22 enough?</p> <p>23 A. Yes.</p> <p>24 Q. I'm going to hand you what I've</p> <p>25 marked as Exhibits 1 and 2 and ask you if Exhibit</p> |

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| <p>1 Nos. 1 and 2 are the expert reports that you 2 prepared in the Mullins case. 3 A. Yes, that's correct. This one is 4 on the left, the thicker one, is a combination of 5 several patients and this one on the right, Exhibit 6 No. 2, is a supplemental set of figures 7 specifically from the specimen of Ms. Mullins. 8 Q. And Exhibits No. 1 and 2 represent 9 the complete opinions you're prepared to give in 10 this case; is that fair? 11 A. That's correct. 12 Q. I show you now what's been marked 13 as deposition Exhibit No. 3. That's a Notice of 14 Deposition in this case. 15 A. Yes, I do see it. 16 Q. Have you seen that before today? 17 A. Yes, I did. 18 Q. As a part of Exhibit 3, there's a 19 request attached to it that you produce documents 20 in response to that. 21 A. There are 27 requests. Yes, I've 22 seen that. 23 Q. Did you review those requests? 24 A. Yes, I did. 25 Q. Did you attempt to collect the</p> | <p>1 everything I had pertinent to this case. 2 MR. ORENT: Just to clarify though 3 again, the communication, I believe, was outside of 4 the three areas specified on Number 27. 5 MR. THOMAS: I'm sorry, I did not hear 6 you. 7 MR. ORENT: Under the federal rules 8 your request Number 27, to make the federal rule 9 recognizing the privilege existing between expert 10 and attorneys. 11 With the exception of the three areas 12 that you requested, I believe there were no 13 responsive communications specifically to those 14 three areas. 15 I believe other communications exist 16 that are not discoverable, and that's what the 17 doctor is referring to. 18 MR. THOMAS: Okay. 19 MR. ORENT: I don't believe he withheld 20 anything responsive to the request as written. 21 BY MR. THOMAS: 22 Q. Doctor, you've given depositions 23 before in the Ethicon MDL, correct? 24 A. That is correct. 25 Q. You've testified in connection</p> |
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| <p>1 information contained in those requests and produce 2 it to me today? 3 A. Yes, I gathered all what I could 4 on the thumb drive. 5 Q. And counsel has given me today 6 what I've marked as Exhibit No. 4, which is a thumb 7 drive. Is this the thumb drive that you just 8 described where you attempted to load all of the 9 documents responsive to the Notice of Deposition 10 that you could find to put on the thumb drive? 11 A. That is correct. 12 MR. ORENT: At this point I want to 13 place an objection and notification. We did file a 14 written objection so subject to those written 15 objections that material has been produced. 16 BY MR. THOMAS: 17 Q. To save the time of going through 18 the notice or the thumb drive for right now, can 19 you recall any documents responsive to the Notice 20 of Deposition that you did not include on the thumb 21 drive? 22 A. Well, the communication with 23 lawyers I didn't put. 24 Q. Okay. 25 A. The rest, I think I included</p> | <p>1 with the Bellew case? 2 A. Yes, I did. 3 Q. And you've testified in connection 4 with the Huskey and Edwards cases, correct? 5 A. That is correct. 6 Q. And in those depositions you 7 testified to a methodology that you used to collect 8 specimens, create histopathological slides where 9 appropriate and review those slides. 10 Did you follow the same process in the 11 Mullins case that you followed in the Bellew and 12 Huskey Edwards cases? 13 A. The process is standard. It's not 14 specifically for medical-legal cases or mesh cases. 15 It's a standard histology protocols in a diagnostic 16 pathology lab, so I don't change it. I follow them 17 for each specimen regardless if it's medical-legal 18 or a regular hospital patient. 19 Q. Doctor, my question really meant 20 to eliminate re asking all those questions that 21 were asked in Huskey, Edwards and Bellew. 22 And if we can confirm that you followed 23 the same procedures in the Mullins case that you 24 followed in the prior depositions where you were 25 asked about your procedures then I'm not going to</p> |

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| <p>1 go over that again. Can we confirm that you</p> <p>2 followed the same steps?</p> <p>3 A. Yes, I can confirm that.</p> <p>4 Q. Doctor, what is a neuropathologist?</p> <p>5 A. Neuropathologist?</p> <p>6 Q. Yes.</p> <p>7 A. Neuropathologist is a surgical</p> <p>8 pathologist who is specializing in examining brain</p> <p>9 tissue or spinal cord. Sometimes it's the</p> <p>10 subspecialty people do just neuropathology;</p> <p>11 sometimes there is cross-coverage.</p> <p>12 In our institution we have a</p> <p>13 neuropathologist but it's only one. Sometimes he</p> <p>14 goes away on meetings, so we cover neuropathology.</p> <p>15 Q. Are you a neuropathologist?</p> <p>16 A. I'm cross-covering neuropathology</p> <p>17 when he is away but I have not specialized in</p> <p>18 neuropathology.</p> <p>19 Q. Are you board certified in</p> <p>20 neuropathology?</p> <p>21 A. No, and you don't have to be board</p> <p>22 certified in neuropathology because surgical</p> <p>23 pathology includes neuropathology.</p> <p>24 I mean, you can sub specialize further</p> <p>25 down, but it depends on specific institution.</p> | <p>1 transvaginal. I mean, why would I consult a</p> <p>2 neuropathologist?</p> <p>3 Q. Just a simple yes or no question?</p> <p>4 A. No, I didn't. There was no</p> <p>5 purpose.</p> <p>6 Q. Did you consult any neuropathology</p> <p>7 textbooks in connection with your opinions in this</p> <p>8 case?</p> <p>9 A. Specifically just recently?</p> <p>10 Q. Any time during your work in this</p> <p>11 case?</p> <p>12 A. Not in this case. I opened and</p> <p>13 read several neuropathology books when I was doing</p> <p>14 research in meshes. It's not just neuropathology</p> <p>15 books, I mean, neuropathology is described in</p> <p>16 general surgical pathology books. Because I've</p> <p>17 been in this field for three years.</p> <p>18 Q. I understand. Just specific</p> <p>19 questions, we'll get done quicker if you answer</p> <p>20 "yes" or "no", if you can, and I'm not trying to</p> <p>21 pin you down.</p> <p>22 Is it your belief that neuropathology</p> <p>23 has no role in understanding the presence of nerves</p> <p>24 in the pelvic floor?</p> <p>25 MR. ORENT: Objection to form.</p> |
| Page 11 | Page 13 |
| <p>1 Because some institutions have a large number of</p> <p>2 specialized cases and some institutions they cover</p> <p>3 broad range.</p> <p>4 Q. You said you had a</p> <p>5 neuropathologist at St. Michael's?</p> <p>6 A. Yes, we do.</p> <p>7 Q. What is the person's name?</p> <p>8 A. Dr. David Munoz.</p> <p>9 Q. Is that the only neuropathologist</p> <p>10 at St. Michael's?</p> <p>11 A. Right now, yes.</p> <p>12 Q. Did you consult with Doctor --</p> <p>13 what's his last name?</p> <p>14 A. Munoz.</p> <p>15 Q. M-U-N-O-Z?</p> <p>16 A. Yes.</p> <p>17 Q. Did you consult with Dr. Munoz in</p> <p>18 connection with any of the opinions that you've</p> <p>19 given in this case?</p> <p>20 A. No.</p> <p>21 Q. Did you consult with any</p> <p>22 neuropathologist in connection with the opinions</p> <p>23 you've given in this case?</p> <p>24 A. We're not talking about brain</p> <p>25 tumors; we're talking about sub tissue</p> | <p>1 THE WITNESS: Yeah, actually the form</p> <p>2 of the question is quite bizarre.</p> <p>3 Because neuropathology is part of</p> <p>4 surgical pathology. So I'm a surgical pathologist</p> <p>5 I'm examining -- yes, there is a field of</p> <p>6 neuropathology when you specialize in that.</p> <p>7 If you take a combination of peripheral</p> <p>8 nerves as part of neuropathology, then I can say</p> <p>9 yes, there is a part of neuropathology. But as I</p> <p>10 said, it's still within surgical pathology.</p> <p>11 This separation is somewhat artificial.</p> <p>12 You probably don't understand exactly how such</p> <p>13 specialization works. Probably that's where it's</p> <p>14 coming from.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Perhaps. Do you know a Kenneth</p> <p>17 Aldape, A-L-D-A-P-E?</p> <p>18 A. No.</p> <p>19 Q. Lorraine Kalia, K-A-L-I-A?</p> <p>20 A. No.</p> <p>21 Q. Julia Keith?</p> <p>22 A. No.</p> <p>23 Q. Tim Rasmus Kiehl, K-I-E-H-L?</p> <p>24 A. The names might be similar. I</p> <p>25 mean, a couple of those names are the same as a</p> |

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| <p style="text-align: right;">Page 14</p> <p>1 couple of neuropathologists in Toronto, I believe, 2 but I don't know their first names. 3 Q. My information is these 4 neuropathologists are affiliated with the 5 University of Toronto. 6 A. Yes, so Dr. Kiehl is practicing at 7 UHN and I think there was another name that also 8 practices at UHN. It's a different institution. 9 The U of T affiliated hospital is called UHN. 10 Q. There's special neuropathology 11 journals, aren't there? 12 A. Yes, there are. 13 Q. Do you subscribe to any? 14 A. No. 15 Q. So fair to say you don't serve on 16 the editorial board of any neuropathology journals, 17 true? 18 A. No, that's true. 19 Q. Is there any reason for you to 20 consult with a neuropathologist to understand how 21 nerves function in the pelvic floor? 22 A. Not really. The only reason I 23 would go to a neuropathologist when there is 24 something I don't know and I cannot find answers in 25 regular books, something which comes from</p> | <p style="text-align: right;">Page 16</p> <p>1 Q. And what question did you ask him? 2 What stain do you use for what? 3 A. When we started our research in 4 meshes, the question was, if the nerve's ingrown. 5 So this is kind of basic question. 6 Q. Sorry, if the nerves what? 7 A. Grow into the mesh. So this was a 8 basic question. But then I was thinking, okay, so 9 I need to make sure that I'm not missing anything 10 and I started thinking of possible scenarios, how 11 nerves can be affected by the mesh. 12 Are they going atrophic, can they 13 disappear completely? And if they go atrophic, you 14 can see atrophy in the nerve with any stain, 15 because the area becomes empty, sort of ooze, the 16 Schwann cells disappear, their axons, this is a 17 basic knowledge. 18 And I ask him if he's using something 19 else, and he was using exactly what I was using. 20 Q. So is it fair to understand that 21 you confirmed with Dr. Munoz your choice of the 22 S100 stain for nerves? 23 A. No, that was not about the S100. 24 Q. What stain specifically was it 25 about?</p> |
| <p style="text-align: right;">Page 15</p> <p>1 experience. We are talking about basic function. 2 Q. In Canada, is there a board 3 certification for your position as anatomical 4 pathologist? 5 A. Yes, there is. 6 Q. Is there a board certification for 7 neuropathologists? 8 A. I'm not sure, but we are 9 practicing neuropathology with this anatomical 10 pathology certification. 11 Q. As far as you recall, you haven't 12 consulted with any neuropathologists in connection 13 with your work in this mesh litigation; fair? 14 MR. ORENT: Objection. 15 THE WITNESS: Not for this specific 16 case. Earlier, when I started research, I ask a 17 few questions which stain sometimes it was better 18 to use when there is pathology of nerves. 19 BY MR. THOMAS: 20 Q. Who did you ask? 21 A. Dr. Munoz, but I think it was even 22 before the litigation started. 23 Q. And what did you ask Dr. Munoz? 24 A. Which stains he was using, if he 25 was using something different that I was using.</p> | <p style="text-align: right;">Page 17</p> <p>1 A. If anything else he's using to 2 examine nerve atrophy or degeneration. 3 Q. And what were you using to analyze 4 that question? 5 A. Just locating H&E. 6 Q. And Dr. Munoz said that was what 7 he was using to analyze the same question? 8 A. He said that you can see it on 9 H&E, but there are a number of other stains to 10 examine for nerve atrophy. 11 Q. And what stains did he tell you 12 that you could use, other than H&E? 13 A. Well, you can see some of the 14 atrophy on S100 -- I don't remember exactly what he 15 said because it was three years ago, because now 16 what I remember it might be coming from different 17 sources, so from my own experience. 18 Q. Do you have a specific 19 recollection of talking to any neuropathologist who 20 gave you any information about how to conduct your 21 investigation into these meshes? 22 A. I don't understand your question. 23 Q. You've told me about conversation 24 you had with Dr. Munoz. Do you have a specific 25 recollection, you remember having any conversations</p> |

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| <p style="text-align: right;">Page 18</p> <p>1 with any neuropathologists about how to conduct</p> <p>2 your work in these cases?</p> <p>3 A. Why would I?</p> <p>4 Q. I'm just asking you if you did or</p> <p>5 not?</p> <p>6 A. No, I didn't.</p> <p>7 Q. Thank you. Now, Exhibit No. 1 and</p> <p>8 Exhibit No. 2 are your reports in this case; we</p> <p>9 talked about that already. They contain a number</p> <p>10 of images?</p> <p>11 A. That's correct.</p> <p>12 Q. Have you supplied copies of all</p> <p>13 those images on this thumb drive?</p> <p>14 A. No, because they're already</p> <p>15 included in the report. I can produce them for you</p> <p>16 separately.</p> <p>17 Q. Do you have digital images of the</p> <p>18 slides in this report?</p> <p>19 A. Of course.</p> <p>20 Q. But they're not on the thumb</p> <p>21 drive?</p> <p>22 A. No, because they're already in the</p> <p>23 report.</p> <p>24 Q. Do you have images of the tissue</p> <p>25 samples that are contained in the report that are</p> | <p style="text-align: right;">Page 20</p> <p>1 Q. Okay. And from what tissue</p> <p>2 samples did you take them?</p> <p>3 A. From explanted TVT and</p> <p>4 TVT-O meshes.</p> <p>5 Q. How many TVT?</p> <p>6 A. Oh, that I would have to check</p> <p>7 with my records now. I don't remember now.</p> <p>8 Q. And TVT-O?</p> <p>9 A. It's there, but I don't remember</p> <p>10 now.</p> <p>11 Q. And the TVT and the TVT-O</p> <p>12 specimens that are contained in your report are</p> <p>13 that, are those specimens from the set of specimens</p> <p>14 that you obtained from Dr. Klinge?</p> <p>15 A. No. It's a combination of earlier</p> <p>16 medical-legal cases, patients of St. Michael's</p> <p>17 Hospital, and samples which came within this</p> <p>18 consolidated trial.</p> <p>19 The earlier cases came from different</p> <p>20 law firms.</p> <p>21 Q. Do you know what I'm referring to?</p> <p>22 You talked about the Bellew case, the set of slides</p> <p>23 that you received from Dr. Klinge, and Dr.</p> <p>24 Kreutzer, 22 TVT and TVT-O samples?</p> <p>25 A. My recollection is I was contacted</p> |
| <p style="text-align: right;">Page 19</p> <p>1 not in the report?</p> <p>2 A. But we took those images together</p> <p>3 with your expert.</p> <p>4 Q. I'm just asking you if you have</p> <p>5 them?</p> <p>6 A. I should have them, yeah.</p> <p>7 Q. Okay?</p> <p>8 A. Because we were taking them -- he</p> <p>9 would take picture. I would take picture of the</p> <p>10 same field.</p> <p>11 Q. But there are images that you have</p> <p>12 of the tissue samples that are contained in your</p> <p>13 report that are not produced on this thumb drive,</p> <p>14 correct?</p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: There should be. I was</p> <p>17 not using them. I was just recording together with</p> <p>18 your expert when I received the specimens.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Okay. And if you go to -- let me</p> <p>21 just ask this question.</p> <p>22 What is the source of the images that</p> <p>23 are contained in your report? Where did you get</p> <p>24 them?</p> <p>25 A. I took them.</p> | <p style="text-align: right;">Page 21</p> <p>1 by Anderson Law and I'm not sure when -- I don't</p> <p>2 remember exactly where the package came from, but</p> <p>3 all my communication was with the Anderson Law.</p> <p>4 Q. I understand that, Doctor, but in</p> <p>5 the Bellew case you testified at length about a set</p> <p>6 of 22 TVT and TVT-O samples that you had received</p> <p>7 from Mr. Anderson that had previously been reviewed</p> <p>8 by Dr. Kreutzer and by Doctor Klinge?</p> <p>9 A. Kreutzer for sure; I'm not sure</p> <p>10 about Doctor Klinge. There were no records, or</p> <p>11 maybe there was records but I just don't remember</p> <p>12 them.</p> <p>13 I didn't contact specifically Doctor</p> <p>14 Klinge, or he didn't contact me specifically about</p> <p>15 these samples.</p> <p>16 Q. Are the images of the TVT and the</p> <p>17 TVT-O slides that are in your report in this case</p> <p>18 from the same set of slides that Dr. Kreutzer</p> <p>19 reviewed?</p> <p>20 A. Some of them could be. Again, I</p> <p>21 don't remember now. It would be difficult to trace</p> <p>22 them back.</p> <p>23 Q. Do you have somewhere a key that</p> <p>24 shows whose tissue this is in the report?</p> <p>25 A. In the report, the way the images</p> |

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| <p style="text-align: right;">Page 22</p> <p>1 were saved during my work, they would be usually 2 saved in folders for specific expert report. 3 Q. Let's go to page 19 of your 4 report, please, Exhibit No. 1? 5 A. So if we open these images, I 6 specify if the image is coming from consolidated 7 trial cases, which I received just recently, or if 8 the images are of additional cases, and additional 9 I meant previous TVT and TVT-O cases which I 10 received during the course of my work on expert of 11 possible Bellew case and others. 12 Q. How many consolidated cases do you 13 have images for, individual plaintiffs? 14 A. Like four, three. Three, four. 15 Some specimens came as bare mesh, had difficulty 16 embedding -- well, we embedded them but there was 17 not much in there. 18 Q. I understand. I'm just trying to 19 understand what you're working from. 20 So you have three or four tissue 21 samples from plaintiffs in the consolidated cases, 22 correct? 23 A. That is correct. 24 Q. What kind of mesh is that? 25 A. TVT or TVT-O.</p> | <p style="text-align: right;">Page 24</p> <p>1 embedded surgical number. 2 Because they're all spread within 3 almost three years, some of them can be traced; 4 some of them would be difficult to trace. 5 Q. Is it fair to understand that 6 looking at the report, where you identify images 7 from additional TVT cases, you're unable to tell me 8 from what case that image comes from? 9 MR. ORENT: Objection. 10 THE WITNESS: In some cases I can, and 11 some cases I cannot. I can tell that you all of 12 them came from TVT and TVT-O because I kept strict 13 records for that. 14 But I didn't keep strict records for 15 specific cases, at least at the beginning. 16 BY MR. THOMAS: 17 Q. Okay. In those places where you 18 can identify the patient, did you do so in your 19 report? 20 A. No. 21 Q. Why not? 22 A. But they are not in this trial -- 23 and they may be confidential. And why would I? 24 Q. But there are images in this 25 report that don't have identifying information --</p> |
| <p style="text-align: right;">Page 23</p> <p>1 Q. Okay. And so in your report, 2 where you refer to images of consolidated cases, is 3 it fair to say that those images come from the 4 three to four tissue samples that you got from the 5 consolidated cases? 6 A. That's correct. 7 Q. If you go to page 21? 8 A. Yes. 9 Q. Page 21 identifies in Figure Set 10 1c, images of additional TVT cases; what does that 11 mean? 12 A. That means this image comes from 13 previous TVT and TVT-O cases, or cases I received 14 previously. 15 Q. Can you tell by looking at this 16 whether it's a medical-legal or whether it's 17 something that came through St. Michael's? 18 A. It would have to be sort of 19 picture matching. I would have to open the folders 20 which contain previous reports. 21 It all depends how the figure was 22 taken. If it was taken by older camera, it didn't 23 record the case number. 24 Now, for some newer cases the images 25 were scanned and when the scanner works, there is</p> | <p style="text-align: right;">Page 25</p> <p>1 none of them have identifying information? 2 A. They have one single identifying 3 information which is important: TVT or TVT-O. 4 Everything else doesn't matter. 5 Q. But I can't take this, go into 6 your file and figure out where this slide is, can 7 I? 8 A. I'm telling you it's all TVT and 9 TVT-O. What else do you need to know? 10 Q. Am I able to take this thumb drive 11 and figure out which slide is which patient on 12 page 21? 13 MR. ORENT: Objection. I think what 14 the doctor is explaining is that these are all from 15 prior reports served on you. 16 THE WITNESS: Most of them are. You 17 can go to older reports and find them. 18 BY MR. THOMAS: 19 Q. Why didn't you say "from the 20 Edwards case" to tell us where it came from? 21 A. Why would I? I don't understand 22 the question. I mean, this is an opinion about TVT 23 and TVT-O. 24 I am not making an opinion about 25 Edwards or any other specific patient. I am giving</p> |

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| <p style="text-align: right;">Page 26</p> <p>1 you opinion about TVT-O as a product.</p> <p>2 Q. Do you maintain your sets of these</p> <p>3 slides by individual plaintiff?</p> <p>4 A. In some cases, yes. If there is a</p> <p>5 generated report because that is a specific</p> <p>6 plaintiff, I save them as separate folder.</p> <p>7 But remember those 23 or 22 cases when</p> <p>8 they came as a bulk and I did not produce any</p> <p>9 specific reports for specific patients, individual</p> <p>10 patients. They were all saved in one folder.</p> <p>11 Q. Okay?</p> <p>12 A. Which was just additional --</p> <p>13 didn't keep record for that.</p> <p>14 Q. Are the files on this thumb drive,</p> <p>15 Exhibit 4, marked by individual plaintiff?</p> <p>16 A. No. As I said, I didn't include</p> <p>17 figures because they were included in the report</p> <p>18 already.</p> <p>19 If you want me to include these</p> <p>20 specific figures, I can do that. But it will not</p> <p>21 be possible to trace specific picture, specific</p> <p>22 patient.</p> <p>23 And that was not the purpose because</p> <p>24 the purpose was to give an opinion about TVT-O or</p> <p>25 TVT as a product, not to give opinion for specific</p> | <p style="text-align: right;">Page 28</p> <p>1 Q. For the original tissue samples</p> <p>2 that you received from Dr. Kreutzer, the 22 or 23</p> <p>3 TVT or TVT-O, did you know that those samples,</p> <p>4 tissue samples, were also analyzed by Dr. Jordi,</p> <p>5 using analytical chemistry?</p> <p>6 A. The name sounds familiar but I</p> <p>7 don't know details. I don't remember, sorry. I</p> <p>8 don't remember specific details, what was done in</p> <p>9 that time.</p> <p>10 Q. Have you ever seen any analytical</p> <p>11 chemistry testing on the 22 or 23 TVT samples that</p> <p>12 you received from Dr. Kreutzer?</p> <p>13 A. I don't recall specific details.</p> <p>14 I could have seen something, I could have not, it's</p> <p>15 been quite a long time ago.</p> <p>16 Q. Did you ever request that</p> <p>17 analytical chemistry testing be conducted on any of</p> <p>18 the mesh samples that you've analyzed?</p> <p>19 A. No. I have my own methodology in</p> <p>20 this; I describe what I see. Why would I ask</p> <p>21 somebody else to do something else?</p> <p>22 Q. So is it fair to understand that</p> <p>23 for Exhibits Number 1 and 2, which is your report</p> <p>24 and supplemental report, that all of the images in</p> <p>25 here are TVT or TVT-O manufactured by Ethicon?</p> |
| <p style="text-align: right;">Page 27</p> <p>1 plaintiffs.</p> <p>2 Q. Exhibit No. 2 is a supplemental --</p> <p>3 micro photographs. You identify those as from the</p> <p>4 specimen of Ms. Elizabeth Mullins?</p> <p>5 A. That is correct.</p> <p>6 Q. Is Elizabeth Mullins -- strike</p> <p>7 that. Did you share this tissue with Ethicon?</p> <p>8 A. Yes, I mailed it a week ago.</p> <p>9 Q. Why did you identify this by</p> <p>10 patient name and not identify the others in your</p> <p>11 report by patient name?</p> <p>12 A. Because it was a single case</p> <p>13 specifically supplemented for one specific patient.</p> <p>14 Q. So this is one of the three or</p> <p>15 four TVT, TVT-O cases that you reviewed for</p> <p>16 consolidated plaintiffs?</p> <p>17 A. Might be an additional to the</p> <p>18 three or four.</p> <p>19 Q. Okay?</p> <p>20 A. So it could be fifth, or fourth.</p> <p>21 Q. Okay. Do you expect to receive</p> <p>22 any more tissue samples from the consolidated</p> <p>23 plaintiffs?</p> <p>24 A. No. As far as I would understand</p> <p>25 this is all what we have at this point.</p> | <p style="text-align: right;">Page 29</p> <p>1 A. Yes. Some images were taken from</p> <p>2 publications, so there was one or two panels from</p> <p>3 different mesh manufacturer.</p> <p>4 But the rest, when the pictures were</p> <p>5 individual, they were all of TVT or TVT-O explanted</p> <p>6 specimens.</p> <p>7 Q. Are you able to tell me sitting</p> <p>8 here today -- strike that.</p> <p>9 Let's go to Exhibit 3, please. Number</p> <p>10 15?</p> <p>11 A. Yes.</p> <p>12 Q. Number 15 asks for all materials</p> <p>13 including but not limited to any protocol</p> <p>14 specimens, slide raw data interim and final test</p> <p>15 results, log laboratory books, notes, photographs,</p> <p>16 photo micrographs and any other documents relating</p> <p>17 to the pristine polypropylene control you tested by</p> <p>18 exposure to formalin for up to four months</p> <p>19 referenced on page 17 of your report in this case.</p> <p>20 Is there any information on the thumb</p> <p>21 drive from Exhibit 4 for that?</p> <p>22 A. The entire protocol is really</p> <p>23 simple. It was included in the paper, so it is on</p> <p>24 the thumb drive; the paper is on the thumb drive.</p> <p>25 I didn't have anything in addition to that.</p> |

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|---|--|
| <p style="text-align: right;">Page 30</p> <p>1 Q. Is there any lab notebook?</p> <p>2 A. No, I mean --</p> <p>3 Q. Are there any photographs?</p> <p>4 A. All photographs I had, I included</p> <p>5 there.</p> <p>6 Q. So whatever you have related to</p> <p>7 the formalin exposed polypropylene control is on</p> <p>8 the thumb drive?</p> <p>9 A. In the report. The pictures are</p> <p>10 on the report. The paper with description of the</p> <p>11 experiment is on the thumb drive.</p> <p>12 Q. What kind of polypropylene was</p> <p>13 tested with formalin?</p> <p>14 A. What do you mean, what kind? I</p> <p>15 tested meshes of different manufacturers including</p> <p>16 Ethicon TVT.</p> <p>17 Q. So you did use an Ethicon Prolene</p> <p>18 mesh in the formalin control test?</p> <p>19 A. It was TVT.</p> <p>20 Q. Okay.</p> <p>21 A. It was a piece of TVT, a few</p> <p>22 pieces of TVT put in formalin.</p> <p>23 Q. When you say you put it in</p> <p>24 formalin, did you do anything other than just put</p> <p>25 it in a jar?</p> | <p style="text-align: right;">Page 32</p> <p>1 Q. Okay. Tell me what that</p> <p>2 experiment does?</p> <p>3 A. I did the same thing as I did for</p> <p>4 formalin exposure. I took pieces of mesh and put</p> <p>5 them in solutions of hydrogen peroxide, hydrogen</p> <p>6 peroxide with catalysts, few strong acids,</p> <p>7 solvents, and just they are stored in these</p> <p>8 solutions.</p> <p>9 Q. How many pieces of mesh are you</p> <p>10 testing?</p> <p>11 A. It's hard to say now. It might be</p> <p>12 over 20 small pieces.</p> <p>13 Q. And how are they stored right now?</p> <p>14 A. In a dark room in a cabinet.</p> <p>15 Q. In a vial?</p> <p>16 A. What do you mean, vial?</p> <p>17 Q. Are they in a container with a</p> <p>18 cover on them?</p> <p>19 A. Yes, of course. Some of them are</p> <p>20 acids and they're in glass containers.</p> <p>21 Q. What temperature are they being</p> <p>22 stored?</p> <p>23 A. Just room temperature.</p> <p>24 Q. Do you have a protocol that you</p> <p>25 wrote up for this test?</p> |
| <p style="text-align: right;">Page 31</p> <p>1 A. They were kept in formalin, in a</p> <p>2 jar, and then they were put in the cassette for</p> <p>3 tissue processing and then they went through the</p> <p>4 whole process of xylene alcohol and everything else</p> <p>5 and then I had slides made.</p> <p>6 Q. And no analytical chemistry done</p> <p>7 of that control, correct?</p> <p>8 A. Why would I? I'm doing histology.</p> <p>9 Q. I understand. No analytical</p> <p>10 chemistry; is that correct?</p> <p>11 A. That is correct.</p> <p>12 Q. Thank you. Number 19.</p> <p>13 A. Yes.</p> <p>14 Q. "Request all materials related</p> <p>15 to testing of intentionally oxidized</p> <p>16 polypropylene that had not been</p> <p>17 implanted or exposed to formalin."</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. Is there any information on</p> <p>21 Exhibit No. 4 related to that kind of testing?</p> <p>22 A. No, because the test is still in</p> <p>23 progress. I mean, I kept part of mesh in different</p> <p>24 solutions and I haven't taken them out yet. I</p> <p>25 haven't examined them yet.</p> | <p style="text-align: right;">Page 33</p> <p>1 A. No. The only protocol I used was</p> <p>2 there was a published paper, they introduced this</p> <p>3 stimulated body environment -- simulated, not</p> <p>4 stimulated. Simulated body environment. Hydrogen</p> <p>5 peroxide was the catalyst. Catalyst is a chromium</p> <p>6 salt.</p> <p>7 Q. Cobalt chloride?</p> <p>8 A. Probably.</p> <p>9 Q. That's Dr. Guelcher's paper?</p> <p>10 A. I'm not sure if it's his paper,</p> <p>11 it's another paper. But anyway, I'm testing his</p> <p>12 protocol. I followed exactly the description in</p> <p>13 the paper and kept it in the solution for almost a</p> <p>14 year by now, but it's still too early to take it</p> <p>15 out.</p> <p>16 Q. Why is it still too early to take</p> <p>17 it out?</p> <p>18 A. Because based on my analysis of</p> <p>19 the specimens explanted from the body I can barely</p> <p>20 see the degradation bark after a year in the body.</p> <p>21 So if I take them now it would be too early.</p> <p>22 I may just waste samples, so I have to</p> <p>23 wait for probably a few extra months or maybe</p> <p>24 another year. Because by year two or 1 1/2 years</p> <p>25 in the body, the bark becomes visible in</p> |

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| <p style="text-align: right;">Page 34</p> <p>1 100 percent of the cases. 2 If I take them out by 12 months, I may 3 or may not see something and then it would -- I'll 4 just waste samples. 5 Q. Did you prepare the solution in 6 which these samples are stored? 7 A. Yes, I did. 8 Q. And what is the recipe for the 9 solution that you used? 10 A. It's written in the original paper 11 I used for the -- 12 Q. Can you tell me what the original 13 paper is? 14 A. I'd have to check now. 15 Q. And how many samples are stored? 16 A. As I said, probably over 20. 17 Q. And how many different kinds of 18 mesh are being tested? 19 A. There is one from one 20 manufacturer, and then -- four types of mesh. 21 Q. How many Ethicon meshes are being 22 tested? 23 A. At least one. 24 Q. What kind? 25 A. It's written on the jars. I may</p> | <p style="text-align: right;">Page 36</p> <p>1 A. At least four different type of 2 mesh. I would have to check with the labels what 3 is written there, what manufacturers, what mesh was 4 put in there. I don't remember. It's been a year. 5 Q. Are you working with anybody else 6 on that experiment? 7 A. No. 8 Q. This is solely your work? 9 A. Yes. 10 Q. Did you consult with anybody about 11 the kind of solution that you would use for your 12 experiment? 13 A. No. Whom I would consult? Nobody 14 did it before. The only information I extracted 15 was from that specific simulation body environment 16 simulation from the paper. 17 Q. You know Dr. Guelcher has tried to 18 insulate oxidized polypropylene, don't you? 19 MR. ORENT: Objection. 20 THE WITNESS: I know that he did an 21 experiment, and he asked me what I see. I said 22 it's too early, I'm not going to take them out yet. 23 I will keep them a little longer. 24 BY MR. THOMAS: 25 Q. Did Dr. Guelcher tell you he had</p> |
| <p style="text-align: right;">Page 35</p> <p>1 have to check later. 2 Q. Doctor, do you have an inventory 3 of what's in each vial written down? 4 A. It's written on the jar. 5 Q. Is it written down on a piece of 6 paper anywhere? 7 A. No. 8 MR. ORENT: Objection. 9 BY MR. THOMAS: 10 Q. Is it written in a computer 11 somewhere? 12 A. No, just on jars. Jars label when 13 the case was put and what type of mesh was put in. 14 Q. When did you start this 15 experiment? 16 A. Last September. 17 Q. So it's been a full year? 18 A. Yes. 19 Q. And did you put the mesh in this 20 solution in these 20 or so samples all at the same 21 time? 22 A. Within two weeks. 23 Q. All right. As I understand it, 24 there are at least four different mesh 25 manufacturers that are a part of this experiment?</p> | <p style="text-align: right;">Page 37</p> <p>1 intentionally oxidized polypropylene by exposing it 2 to some chemical solution? 3 MR. ORENT: Objection. 4 THE WITNESS: Yes, he did. 5 BY MR. THOMAS: 6 Q. Did you ask him to have that mesh 7 so that you could determine whether this 8 intentionally oxidized polypropylene absorbed 9 stain? 10 MR. ORENT: Objection. 11 THE WITNESS: No. 12 BY MR. THOMAS: 13 Q. Why not? 14 MR. ORENT: Objection. 15 THE WITNESS: Because I'm doing my own 16 experiment and I believe I need to keep it for at 17 least a year and a half. 18 BY MR. THOMAS: 19 Q. Did you discuss with Dr. Guelcher 20 the scope of his experiment? 21 MR. ORENT: Objection. At this point, 22 Counsel, I think you're getting into -- I think you 23 need to clarify whether your questions are in the 24 context of litigation or research. 25 To the extent it's in litigation it's</p> |

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| <p style="text-align: right;">Page 38</p> <p>1 covered by privilege and I would instruct the</p> <p>2 witness not to answer under the rules. But to the</p> <p>3 extent that you're discussing research, I think</p> <p>4 that's fair game to discuss.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Okay. From a research</p> <p>7 perspective, did you have any discussions with Dr.</p> <p>8 Guelcher about his experiment?</p> <p>9 A. It's work in progress so it's</p> <p>10 privileged to researchers, I guess, at this point.</p> <p>11 Q. Are you going to assert a</p> <p>12 privilege for your research?</p> <p>13 A. For research information, yes.</p> <p>14 Q. Okay. And you asserted a</p> <p>15 litigation privilege, which I don't think is</p> <p>16 appropriate -- I'm not arguing with you. You said</p> <p>17 there's no research privilege. Now he's trying to</p> <p>18 assert a research privilege?</p> <p>19 MR. ORENT: No, what I said was in</p> <p>20 terms of legal -- in terms of legal privileges that</p> <p>21 I can, that I have, that I have an attorney-client --</p> <p>22 excuse me, a attorney work product under the Rule</p> <p>23 26.</p> <p>24 Rule 26 specifically allows for expert</p> <p>25 witnesses to consult with one another under the</p> | <p style="text-align: right;">Page 40</p> <p>1 this.</p> <p>2 MR. THOMAS: Thank you.</p> <p>3 -- RECESS AT 9:42 --</p> <p>4 -- UPON RESUMING AT 9:43 --</p> <p>5 MR. ORENT: We can go back on the</p> <p>6 record.</p> <p>7 I'll just say for the record over the</p> <p>8 break I just explained to Dr. Iakovlev what the</p> <p>9 highly confidential designation is and that all the</p> <p>10 lawyers in this litigation have all signed on to</p> <p>11 it.</p> <p>12 Confidentiality agreement whereby there</p> <p>13 are limited distribution on each side as to who can</p> <p>14 receive highly confidential information and that</p> <p>15 after discussing it I believe the witness is</p> <p>16 comfortable with the designation and will proceed</p> <p>17 to answer.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. Thank you. Have you have</p> <p>20 discussed with Dr. Guelcher the results of his</p> <p>21 test?</p> <p>22 A. Yes, I asked him what he saw.</p> <p>23 Q. And what did he tell you?</p> <p>24 A. He said that there is flaking on</p> <p>25 the surface early, it's not confluent but there are</p> |
| <p style="text-align: right;">Page 39</p> <p>1 2010 amendments to the federal rules.</p> <p>2 So, what I was clarifying is that it is</p> <p>3 my privilege to seek and to utilize for my client,</p> <p>4 and that's what I was exercising with regard to</p> <p>5 non-research thought processes for litigation.</p> <p>6 To the extent Dr. Iakovlev has</p> <p>7 proprietary interests in research that is ongoing</p> <p>8 or may be ongoing, that's up to him as to whether</p> <p>9 or not -- and I know that on both sides in this</p> <p>10 mesh litigation have previously taken a position</p> <p>11 that those sort of things are not discoverable.</p> <p>12 To the extent the doctor is</p> <p>13 comfortable, I'd be happy to designate this portion</p> <p>14 of the transcript highly confidential and allow the</p> <p>15 witness to answer.</p> <p>16 THE WITNESS: I also need to add that</p> <p>17 that experiment is not in my opinions. I was not</p> <p>18 base my opinions on any part of that experiment.</p> <p>19 And I'm not really sure why you asking me these</p> <p>20 questions.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Because I get to ask them.</p> <p>23 MR. ORENT: If I can just have a minute</p> <p>24 with the witness and explain what the highly</p> <p>25 confidential designation means, that may clarify</p> | <p style="text-align: right;">Page 41</p> <p>1 some flakes forming.</p> <p>2 I said it might be too early, because</p> <p>3 he did it I think on six weeks or so, maybe more,</p> <p>4 maybe up to three months.</p> <p>5 I said, well, I keep my specimens for</p> <p>6 at least a year and a half because I believe that</p> <p>7 that's much time you need to make it visible by my</p> <p>8 techniques. Maybe by SCM we can see a little bit</p> <p>9 earlier, and we stopped at that.</p> <p>10 Q. Do you know whether he conducted</p> <p>11 any analytical chemistry testing on any of the mesh</p> <p>12 he analyzed?</p> <p>13 A. I think he did.</p> <p>14 MR. ORENT: Objection.</p> <p>15 THE WITNESS: I don't remember at this</p> <p>16 point. It's not my specifically methodology, so I</p> <p>17 didn't do these things.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. Did you have discussions with Dr.</p> <p>20 Guelcher about trying to stain the polypropylene</p> <p>21 that he had intentionally oxidized?</p> <p>22 A. He asked me. I said it's too</p> <p>23 early.</p> <p>24 Q. Okay?</p> <p>25 A. So I said maybe by your methods</p> |

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| <p style="text-align: right;">Page 42</p> <p>1 you can detect it. By my methods, probably I 2 cannot. And I said I will keep my pieces for 3 longer and then we'll see what happens. 4 Q. And how did you decide -- strike 5 that. Did I understand you to say that you have 6 chosen 18 months as the time when you think it will 7 be appropriate to test for oxidation? 8 MR. ORENT: Objection to form. 9 THE WITNESS: Yes. 10 BY MR. THOMAS: 11 Q. And at 18 months is it your 12 intention to remove all of those meshes from the 13 chemical solution and determine whether it's 14 intentionally oxidized? 15 A. Part of it. Probably not all of 16 them in one shot. I will start taking some pieces 17 and examining them see what happens and if I -- 18 depends on what I see, I may keep them longer. 19 Q. And what kind of tests do you 20 propose to run on them after 18 months? 21 A. Histology, what I've done -- what 22 I showed in the paper. 23 Q. The same kind of tests that you've 24 run on the meshes that are contained in your 25 reports?</p> | <p style="text-align: right;">Page 44</p> <p>1 A. They came from some law firms 2 during earlier cases. 3 Q. Okay. And where did you get the 4 chemicals? 5 A. I said, they are in the lab. 6 Q. Okay. So you used materials from 7 the St. Michael's histo lab to put them, and you 8 combined those chemicals in a recipe that you're 9 now exposing this polypropylene to? 10 A. That is correct. These are 11 regular chemicals that are used in histo lab. 12 Q. And the reason why you're doing 13 this test is to determine whether, first, after 14 18 months this polypropylene will oxidize due to 15 exposure to this chemical mixture, correct? 16 A. Could you repeat the question? 17 MR. THOMAS: Can you read it back? 18 -- REPORTER'S NOTE: Question read back 19 as recorded above. 20 THE WITNESS: That's correct. 21 BY MR. THOMAS: 22 Q. And how will you determine whether 23 it's oxidized? 24 A. I would see degradation layer on 25 the surface.</p> |
| <p style="text-align: right;">Page 43</p> <p>1 A. Similar. 2 Q. Any differences? 3 A. Don't plan on anything different 4 at this point. I may, I mean, it's work in 5 progress research. Maybe I'll find something else, 6 I don't know. 7 Q. Are you consulting with anybody 8 else on this particular experiment? 9 A. We discussed it only with Scott 10 Guelcher. 11 Q. And is the mesh that's being 12 tested pristine new mesh? 13 A. Yes. 14 Q. Never been exposed to tissue? 15 A. That is correct. 16 Q. Never been exposed to formalin? 17 A. That is correct. 18 Q. Who is paying for this testing? 19 A. Nobody. I just took chemicals 20 from our histo lab. 21 Q. Did counsel fund this experiment? 22 A. No, there is no additional 23 funding. What funding would I need for it? 24 Chemicals are in the lab. 25 Q. Where did you get the mesh?</p> | <p style="text-align: right;">Page 45</p> <p>1 Q. And that would be by light 2 microscopy? 3 A. Yes. 4 MR. ORENT: Objection. 5 BY MR. THOMAS: 6 Q. Any other analytical technique 7 that you propose to use? 8 A. As I said, none at this point. 9 Q. And as a part of your experiment 10 do you then intend to see whether -- if you are 11 able to oxidize polypropylene, according to your 12 visual observation by light microscopy, will you 13 then see whether the oxidized polypropylene holds 14 stain? 15 A. Yes, that's the way to see it. 16 This just becomes porous and after absorbs stain. 17 Q. And the way you will test that is 18 the same way you've processed the slides in Exhibit 19 No. 1 and 2 -- you'll put them through the sample 20 preparation histology analysis that you've done in 21 all your other cases? 22 A. Can be tried without putting them 23 through histology; you can immerse exposed mesh 24 into the dye solution. 25 Q. Just drop it in the jar?</p> |

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| Page 46 | Page 48 |
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| <p>1 A. Pretty much. If it stains, then</p> <p>2 you can see staining on the surface. That means</p> <p>3 there is a layer of porous polypropylene on the</p> <p>4 surface.</p> <p>5 It's like, this is not stain, this is</p> <p>6 anodized aluminum. So there's porous layer on</p> <p>7 aluminum. If you drop unprepared aluminum in the</p> <p>8 jar with black ink it will not absorb anything</p> <p>9 because it's sealed.</p> <p>10 If you drop it with anodized layer it</p> <p>11 will become black because it will absorb it. It's</p> <p>12 the same technique; it's pretty basic.</p> <p>13 Q. I understand. Thank you.</p> <p>14 Are you aware of a method where you can</p> <p>15 take a piece of pristine mesh that's been exposed</p> <p>16 as you've described, and prepare a histological</p> <p>17 slide of that exposed material without embedding it</p> <p>18 in some other medium?</p> <p>19 A. Let me ask you if I got your</p> <p>20 question right.</p> <p>21 Am I aware of a histological technique</p> <p>22 which will allow me to cut through the mesh without</p> <p>23 embedding it into anything?</p> <p>24 Q. Correct.</p> <p>25 A. No. It has to be embedded into</p> | <p>1 A and B, identified as Figure Set 16 A, is</p> <p>2 identified as "cracking on the surface of TVT mesh</p> <p>3 fibers immediately after removal from the body".</p> <p>4 Where did you get this?</p> <p>5 A. This was a St. Michael's patient.</p> <p>6 So when it was excised I immediately placed it</p> <p>7 under the microscope.</p> <p>8 Q. How did you know it was being</p> <p>9 excised?</p> <p>10 A. What do you mean how do I know?</p> <p>11 We receive specimens.</p> <p>12 Q. Just so I understand -- strike</p> <p>13 that.</p> <p>14 Typically after a surgical procedure</p> <p>15 when mesh is excised the surgeon immediately places</p> <p>16 it in formalin, correct?</p> <p>17 A. Not always.</p> <p>18 Q. Okay.</p> <p>19 A. We receive it fresh, so in this</p> <p>20 case it was fresh.</p> <p>21 Q. And did you discuss with the</p> <p>22 surgeon any of the circumstances of removal?</p> <p>23 A. This was a St. Michael's specimen,</p> <p>24 so I did ask, but I'm not sure if I can go there</p> <p>25 because of the confidentiality issues. It was not</p> |
| Page 47 | Page 49 |
| <p>1 some form of medium to hold it for the knife to cut</p> <p>2 through.</p> <p>3 Q. Have you devised or thought of a</p> <p>4 method to do that?</p> <p>5 A. No. Why would I?</p> <p>6 Q. If you're going to do a histology</p> <p>7 slide of this mesh that's been exposed to chemicals</p> <p>8 after a year and a half, you're going to have to</p> <p>9 put it in some medium before the microtome can cut</p> <p>10 it, correct?</p> <p>11 A. Paraffin.</p> <p>12 Q. So you're going to put the mesh by</p> <p>13 itself in paraffin and cut it from there?</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 A. That's how it's done.</p> <p>17 Q. That's fine. Doctor, on page 82</p> <p>18 of your report?</p> <p>19 A. Yes.</p> <p>20 Q. Are you on page 82? That's where</p> <p>21 I want you to be.</p> <p>22 A. Oh, yes, okay.</p> <p>23 Q. I'm sorry, 83. I apologize, I was</p> <p>24 wrong.</p> <p>25 Page 83 of your report has two images,</p> | <p>1 a medical-legal case.</p> <p>2 Q. Who was the doctor that you</p> <p>3 discussed it with?</p> <p>4 A. I don't know if I can disclose it.</p> <p>5 Q. I'm going to ask you to and if you</p> <p>6 tell me no, you tell me no?</p> <p>7 A. Again, I'm not sure if I can</p> <p>8 disclose that because it is confidential</p> <p>9 information.</p> <p>10 Q. Are you telling me you're not</p> <p>11 going to? That's fine. Tell me you're not going</p> <p>12 to and I'll move on.</p> <p>13 A. No, I will not. I will not</p> <p>14 because I don't want to compromise confidentiality.</p> <p>15 Q. Okay. Can you tell me the nature</p> <p>16 of the conversation you had with this doctor?</p> <p>17 A. Oh, I asked her later on what was</p> <p>18 -- because then I would ask how long it's been in</p> <p>19 the body, some information was on the records and</p> <p>20 just basic information.</p> <p>21 Q. Did you get medical records for</p> <p>22 this mesh?</p> <p>23 A. It was in medical -- in the</p> <p>24 medical records of St. Michael's Hospital.</p> <p>25 Q. Did you produce on the thumb</p> |

13 (Pages 46 to 49)

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| <p style="text-align: right;">Page 50</p> <p>1 drive, Exhibit No. 4, the medical records for the 2 patient that's on page 83? 3 MR. ORENT: Objection. 4 THE WITNESS: No, it's confidential 5 information, St. Michael's Hospital information. 6 And the picture is not coming from a case itself; 7 picture is coming from a publication. 8 BY MR. THOMAS: 9 Q. Well, it's your publication; is 10 that fair? 11 A. Yes. 12 MR. ORENT: Objection. 13 BY MR. THOMAS: 14 Q. Okay? 15 A. But it's not coming from a set of 16 TVT or TVT-O cases which are received within the 17 litigation process. It's coming from a publication 18 and for that publication I had REB approval and 19 there are strict rules what can be disclosed, what 20 cannot be disclosed. 21 Q. How long from the removal of this 22 mesh until the time you looked under the 23 microscope? 24 A. I would say an hour, maybe 25 40 minutes, maybe less.</p> | <p style="text-align: right;">Page 52</p> <p>1 Not only specifically for this case, I 2 asked if you can sometimes help me with what you're 3 excising, or submit it in saline, so it's not 4 exposed to formalin because I needed samples to be 5 put in a glutaraldehyde. This came in saline. 6 BY MR. THOMAS: 7 Q. Was this put in glutaraldehyde 8 before you made this image? 9 A. No, it was put in saline. I 10 received it in saline, I examined it, took pictures 11 and put it in formalin. 12 Q. Other than putting it in saline, 13 was any effort made to clean the mesh prior to the 14 time that you took these images? 15 A. No, just washed them in saline, 16 that's it. 17 Q. Was it washed in saline or just 18 soaked in saline? 19 A. What's the difference? 20 Q. Well, there was no effort to wash 21 it, it was merely stored in saline before you took 22 your images; is that fair? 23 A. You immerse something in fluid; 24 it's being washed. 25 Q. Okay. Go to page 5 of your</p> |
| <p style="text-align: right;">Page 51</p> <p>1 Q. How did you manage to get it so 2 quickly? 3 A. We have a lab in the OR. OR is 4 practically -- I mean, our receiving area for 5 specimens is in OR, it's like there. 6 Q. Did you tell the doctor if she 7 ever got a TVT specimen that you'd like to have it 8 before it was put in formalin? 9 A. No, but I told, I told several 10 physicians and several -- everybody knows that I'm 11 working on meshes, so people know that I'm 12 interested in meshes. 13 Q. My question was, did you tell a 14 doctor to give one to you before it was exposed to 15 formalin? 16 MR. ORENT: Objection. Can I just ask 17 for clarification. Your prior question was -- 18 included the word TVT. Prior testimony on this was 19 that this was not a TVT, I believe. Oh, this is a 20 TVT, I apologize. 21 THE WITNESS: In the earlier, very 22 early when we started working on these meshes, the 23 question was how do I process them for scanning of 24 -- transmission of electron microscopy, and I 25 needed fresh samples.</p> | <p style="text-align: right;">Page 53</p> <p>1 report, please. 2 A. Yes. 3 Q. Down at the bottom of the page, 4 the sentence, it reads: 5 "Immediately after placement in 6 the body, foreign objects become 7 coated with human proteins before 8 appearance of the inflammatory 9 cells." 10 Do you see that? 11 A. Yes. 12 Q. What does that mean? 13 A. It means that anything you put in 14 the body will get coated by serum proteins. 15 Q. How many different kinds of 16 proteins are there in the body? 17 A. Very large number, thousands, 18 maybe millions. 19 Q. Is there a special kind of protein 20 that surrounds the foreign body? 21 A. It's non-specific. The area will 22 be filled with blood immediately, so main proteins 23 are in the serum, so it will be albumin, some 24 immunoglobins, then the blood clotting cascade sets 25 in.</p> |

14 (Pages 50 to 53)

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| Page 54 | Page 56 |
|---|---|
| <p>1 So there will be more of a fibrinogen</p> <p>2 and fibrin, all of those proteins which are</p> <p>3 involved in blood clotting. It depends what</p> <p>4 timeframe we're talking about, immediate coating,</p> <p>5 or minutes or hours or days after.</p> <p>6 Q. Do you know what protein</p> <p>7 adsorption is, A-D-S-O-R-P-T-I-O-N?</p> <p>8 A. You mean adherence of the protein</p> <p>9 to the surface?</p> <p>10 Q. Are you familiar with that?</p> <p>11 A. I mean, that's the term as I</p> <p>12 understand it.</p> <p>13 Q. Do you know chemically how that</p> <p>14 works?</p> <p>15 A. For all proteins?</p> <p>16 Q. For protein adsorption to foreign</p> <p>17 bodies; do you know how it works?</p> <p>18 A. Not the specific chemical details.</p> <p>19 Q. Do you know the extent to which</p> <p>20 the proteins form a bond with the foreign body?</p> <p>21 A. Not the specific details.</p> <p>22 Q. Do you specifically with</p> <p>23 polypropylene -- or strike that. Specifically with</p> <p>24 Prolene, do you have any information about the</p> <p>25 extent to which human proteins form a bond with the</p> | <p>1 analyzed as groups?</p> <p>2 A. Which page number?</p> <p>3 Q. I'm on 82.</p> <p>4 A. Okay.</p> <p>5 Q. 82 is called, "Figure Set 15, TVT</p> <p>6 Meshes Analyzed as a Group".</p> <p>7 And you're doing a statistical analysis</p> <p>8 here of the TVT meshes; is that correct?</p> <p>9 A. That's correct.</p> <p>10 Q. Are the TVT meshes described on</p> <p>11 page 82 the meshes that you got from Dr. Kreutzer?</p> <p>12 A. Some of them.</p> <p>13 Q. How many of them?</p> <p>14 A. I don't remember now. Probably</p> <p>15 about 20 or 19.</p> <p>16 Q. And how many are in this group?</p> <p>17 A. 23.</p> <p>18 Q. So probably 19 or 20 out of 23</p> <p>19 were meshes you got from Dr. Kreutzer?</p> <p>20 A. Probably, but I'm not sure. I</p> <p>21 don't remember now.</p> <p>22 Q. Are you a trained statistician?</p> <p>23 A. No, but I had my statistics when I</p> <p>24 did my research training.</p> <p>25 Q. Okay. Who chose the statistical</p> |
| Page 55 | Page 57 |
| <p>1 Prolene polypropylene?</p> <p>2 MR. ORENT: Objection.</p> <p>3 THE WITNESS: No.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Do you have any information about</p> <p>6 the extent to which saline is adequate to remove</p> <p>7 any proteins that are adsorbed on to the Prolene</p> <p>8 mesh?</p> <p>9 A. No, I think it's irrelevant</p> <p>10 because that mesh which was examined didn't have</p> <p>11 time to dry and couldn't dry because it was in</p> <p>12 saline.</p> <p>13 So if it cracks it means that it had</p> <p>14 time to crack. In this case it couldn't dry.</p> <p>15 Q. There's no analytical chemistry</p> <p>16 done on this, correct?</p> <p>17 A. No.</p> <p>18 Q. There are none; am I correct?</p> <p>19 A. You are correct.</p> <p>20 Q. Thank you. So, you're basing your</p> <p>21 opinion on the cracking, which you claim to be the</p> <p>22 Prolene, based on your visual observation?</p> <p>23 A. That is correct.</p> <p>24 Q. Let's go back to page 82, please</p> <p>25 which is your statistical analysis of TVT meshes</p> | <p>1 method that's employed here?</p> <p>2 A. I did.</p> <p>3 Q. And why?</p> <p>4 A. What do you mean why?</p> <p>5 Q. Why was this method the method you</p> <p>6 chose?</p> <p>7 A. Because it's the method to check</p> <p>8 what I was intending to check.</p> <p>9 Q. And tell me why that is an</p> <p>10 appropriate method for what you have done?</p> <p>11 A. What do you mean?</p> <p>12 Q. Why is this Pearson coefficient?</p> <p>13 A. Pearson coefficient? It's a</p> <p>14 standard correlation coefficient method.</p> <p>15 Q. Are you aware of other statistical</p> <p>16 methods to test your results?</p> <p>17 A. What do you mean? For</p> <p>18 correlation?</p> <p>19 Q. Yes.</p> <p>20 A. Could be Spearman.</p> <p>21 Q. Spearman?</p> <p>22 A. Yes.</p> <p>23 Q. Any others, R-squared?</p> <p>24 A. For correlation?</p> <p>25 Q. Yes.</p> |

15 (Pages 54 to 57)

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| Page 58 | Page 60 |
|---|---|
| <p>1 A. There might be others, but the</p> <p>2 main are Pearson and Spearman; there is not much</p> <p>3 difference between them.</p> <p>4 Q. Is the raw data you used to do</p> <p>5 your statistical correlation on Exhibit 4?</p> <p>6 A. Yes, it is.</p> <p>7 Q. And how is it marked, so if I</p> <p>8 wanted to find it, I could see it?</p> <p>9 A. It's in a separate file it's</p> <p>10 called 23 TVT-O and something else for the chart.</p> <p>11 Q. So if I wanted to have a</p> <p>12 statistician run a different model, all of the data</p> <p>13 he would need to do it is on Exhibit 4?</p> <p>14 A. Yes. It's there.</p> <p>15 Q. Okay. Doctor, since you were last</p> <p>16 deposed, you've had a couple of studies published</p> <p>17 in journals?</p> <p>18 A. Probably more than a couple, yes,</p> <p>19 I did.</p> <p>20 Q. And your deposition notice</p> <p>21 requested communications with the journals about</p> <p>22 publications that you produced. Are those on</p> <p>23 Exhibit 4?</p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: I believe it's</p> | <p>1 was quick answer, right away, that's not in our</p> <p>2 scope.</p> <p>3 Q. So how many journals did not</p> <p>4 accept your publication?</p> <p>5 MR. ORENT: Objection.</p> <p>6 THE WITNESS: I don't remember now.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Okay. Do you have that</p> <p>9 information?</p> <p>10 A. Probably somewhere in the replies</p> <p>11 I can find it.</p> <p>12 Q. Okay. Did you ever disclose to</p> <p>13 the journals to which you submitted these</p> <p>14 publications that some of the work contained in the</p> <p>15 journal publication had been funded by plaintiff's</p> <p>16 counsel?</p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: Nothing was funded by</p> <p>19 plaintiff's counsel. They were litigation cases</p> <p>20 but I didn't get any additional funding to conduct</p> <p>21 the study.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Certainly the slides from Dr.</p> <p>24 Kreutzer were provided to you by plaintiff's</p> <p>25 counsel?</p> |
| Page 59 | Page 61 |
| <p>1 confidential to me as a researcher, privileged.</p> <p>2 They've been published, they've been accepted, they</p> <p>3 are publicly available.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Is the answer to my question no,</p> <p>6 you didn't produce any of those communications?</p> <p>7 A. No, I didn't.</p> <p>8 Q. Do you have such communications?</p> <p>9 A. Acceptance letters, that's about</p> <p>10 it.</p> <p>11 Q. Do you have any comments or</p> <p>12 criticisms from any peer reviewers?</p> <p>13 MR. ORENT: Objection.</p> <p>14 THE WITNESS: There were some.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Do you still have those?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Were any of these articles</p> <p>19 rejected by any journals?</p> <p>20 A. Sometimes I submit to one journal</p> <p>21 they say it's out of scope it's probably best</p> <p>22 suited for another journal so it bounces back.</p> <p>23 I don't remember specific rejection,</p> <p>24 saying that the data isn't reliable. The only way</p> <p>25 -- the only time when the paper was not accepted it</p> | <p>1 MR. ORENT: Objection, argumentative.</p> <p>2 THE WITNESS: I didn't use them.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. In your study? Isn't that what --</p> <p>5 A. I meant I didn't use the stains he</p> <p>6 used. I re-stained on stain slides. Maybe even</p> <p>7 cut the blocks.</p> <p>8 Q. So is it your testimony that all</p> <p>9 of the information that you submitted to the</p> <p>10 journals was unrelated to your medical-legal work?</p> <p>11 A. No. It's not unrelated because</p> <p>12 some samples came for medical-legal purposes.</p> <p>13 Q. And for which you were paid to</p> <p>14 analyze by plaintiff's counsel, correct?</p> <p>15 A. To provide reports.</p> <p>16 Q. And what percentage of the cases</p> <p>17 that you report in the study were cases for which</p> <p>18 you were compensated by plaintiff's counsel?</p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: The study was not</p> <p>21 compensated by anyone. I did it on my own time,</p> <p>22 during my own time, and I don't know why you're</p> <p>23 saying that.</p> <p>24 The percentage of cases which came</p> <p>25 through medical-legal litigation process is</p> |

16 (Pages 58 to 61)

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| <p style="text-align: right;">Page 62</p> <p>1 indicated in the paper.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Okay. We'll get to that in a</p> <p>4 minute.</p> <p>5 In the last year you've traveled and</p> <p>6 made presentations around the world on the research</p> <p>7 that you've done?</p> <p>8 A. Yes, I did.</p> <p>9 Q. Who has funded that work?</p> <p>10 A. Pretty much I did.</p> <p>11 Q. Did anybody subsidize your trips?</p> <p>12 A. No, I mean, we have a specific</p> <p>13 portion of our salary from St. Michael's Hospital</p> <p>14 which is dedicated for presentations. But it's</p> <p>15 within my salary, it's more or less a way of</p> <p>16 getting it through a different tax bracket because</p> <p>17 it's money spent for -- it's within my contract.</p> <p>18 Q. Did you receive any funds from</p> <p>19 plaintiff's counsel for your presentations in the</p> <p>20 last year?</p> <p>21 A. Never.</p> <p>22 Q. The articles that you had worked</p> <p>23 on --</p> <p>24 A. The full answer would be I paid</p> <p>25 for all the trips and I never received any money</p> | <p style="text-align: right;">Page 64</p> <p>1 because it was in a publication.</p> <p>2 Q. Did you obtain permission from the</p> <p>3 patient to do that?</p> <p>4 A. For using the -- we have a</p> <p>5 standard protocol for research. We use material</p> <p>6 for research purpose and I had REB approval.</p> <p>7 Q. Did you obtain permission from the</p> <p>8 patient to use this image?</p> <p>9 A. As I said, each person who enters</p> <p>10 the hospital, academic hospital, St. Michael's</p> <p>11 Hospital, signs agreements or release form and it's</p> <p>12 covered by blanket research regulations.</p> <p>13 Q. Does the patient know that her</p> <p>14 mesh fiber was featured in a publication?</p> <p>15 A. No, I didn't tell her specifically</p> <p>16 to the patient.</p> <p>17 Q. Okay. So the entirety of the</p> <p>18 excised mesh was then placed in paraffin?</p> <p>19 A. I believe so.</p> <p>20 Q. Is there any remaining of the mesh</p> <p>21 explant that was not put in paraffin?</p> <p>22 A. I don't think so. It depends. If</p> <p>23 it's a large piece, which I don't suspect it is,</p> <p>24 there are some remnants which are stored in</p> <p>25 formalin. In this case, probably everything went</p> |
| <p style="text-align: right;">Page 63</p> <p>1 for making presentations or publishing the papers.</p> <p>2 Q. Okay. Let's go back to page 83.</p> <p>3 83 again is the mesh fiber that you looked at under</p> <p>4 light microscopy 40 minutes to an hour after it was</p> <p>5 removed and before it was stored in formalin,</p> <p>6 correct?</p> <p>7 A. That is correct.</p> <p>8 Q. Where is that fiber today?</p> <p>9 A. It's embedded in formalin. The</p> <p>10 specimen went into formalin -- sorry. The specimen</p> <p>11 went to formalin and now it's embedded in paraffin.</p> <p>12 Q. Why is it in paraffin?</p> <p>13 A. To take histological section.</p> <p>14 Q. Have you taken histological</p> <p>15 sections of it yet? Have you taken histological</p> <p>16 sections of this mesh fiber yet?</p> <p>17 A. Yes, I did.</p> <p>18 Q. Are those reported anywhere?</p> <p>19 A. What do you mean? This was St.</p> <p>20 Michael's Hospital patient. I described it, and I</p> <p>21 reported whatever I saw in the microscope.</p> <p>22 Q. Okay.</p> <p>23 A. It's not within the litigation</p> <p>24 process. It's a patient outside of litigation and</p> <p>25 the only way this picture made it into this report</p> | <p style="text-align: right;">Page 65</p> <p>1 to paraffin.</p> <p>2 Q. So there still exists some mesh</p> <p>3 material in paraffin that could be available for</p> <p>4 analysis; fair?</p> <p>5 MR. ORENT: Objection.</p> <p>6 THE WITNESS: For histology?</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Yes.</p> <p>9 A. Yes.</p> <p>10 Q. And have you prepared histological</p> <p>11 slides of the mesh fibers that are contained on</p> <p>12 page 83 of your report?</p> <p>13 A. Yes.</p> <p>14 MR. ORENT: Objection.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. As I understand it, they are not</p> <p>17 part of your report in this case, true?</p> <p>18 A. No. As I said, this patient has</p> <p>19 nothing to do with this report. The only mechanism</p> <p>20 that this paper appeared in this report because it</p> <p>21 was in peer-reviewed publication, that's it. Why</p> <p>22 are we talking about this patient? I don't</p> <p>23 understand.</p> <p>24 Q. And if I wanted you to produce the</p> <p>25 paraffin with the remaining mesh and the slides</p> |

17 (Pages 62 to 65)

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| <p style="text-align: right;">Page 66</p> <p>1 that you have for this mesh, which is depicted on 2 83, would you do that for me? 3 MR. ORENT: Objection. I think you 4 need to deal with the hospital and privacy laws of 5 Canada. I don't think Dr. Iakovlev owns that 6 property, nor -- 7 MR. THOMAS: If he's not going to do 8 it, that's all I want to know. 9 THE WITNESS: No, I will not do that. 10 As I said, the paper is published. It's public, 11 that is why it made it into this report. 12 Everything which belong to St. Michael's and 13 individual patients outside of litigation has 14 nothing to do with this report. 15 BY MR. THOMAS: 16 Q. Did you wait until it was 17 published before you used it in the report? 18 A. Yes, I did. I mean, it was 19 published by the time I produced the report. 20 Q. Okay. Did you use it in any other 21 report prior to the time that it was published in 22 the journal? 23 A. I don't think so. 24 Q. That would have been 25 inappropriate?</p> | <p style="text-align: right;">Page 68</p> <p>1 They see if there can be any harm to the patients, 2 then they approve your methodology. 3 Q. And do you have a written document 4 from the REB that approves your mesh research work? 5 A. Yes. 6 Q. Is there more than one that you 7 have from there? 8 A. There was renewal. 9 Q. Did you submit an application to 10 them for this REB approval? 11 A. Yes, of course. 12 Q. And you have that application 13 still? 14 A. Yes, I should. 15 Q. What other documents did you have 16 in your possession related to your request for, or 17 their approval of your research in meshes? 18 A. Nothing. Just application and 19 their approval letter. 20 Q. Did you have to appear before the 21 REB to represent on your research? 22 A. No, it's a simple, it is a very 23 simple project. I don't do anything to the 24 patient. I don't do anything specific. 25 I do exactly what I do every day, so it</p> |
| <p style="text-align: right;">Page 67</p> <p>1 A. Before it was published, or 2 accepted -- it depends. It's my research project 3 and I'm covered by REB. 4 So if it's within my research and 5 knowledge it would be appropriate because I conduct 6 research, that's information I extract during my 7 research. 8 Q. So if you used it in a report 9 against Ethicon prior to the time that it was 10 published in the journal, that's okay, because it's 11 a product of your independent research under the 12 REB; is that correct? 13 A. Yes. 14 (Reporter sought clarification.) 15 A. Research Ethics Board. 16 Q. Is the Research Ethics Board the 17 Canadian equivalent of the American Institutional 18 Review Board; do you know? 19 A. No, no. 20 Q. What's the difference? 21 A. Ethics board is individual for 22 specific institutions. Each institution has their 23 specific research ethics board. 24 Q. What does the REB do? 25 A. They review your application.</p> | <p style="text-align: right;">Page 69</p> <p>1 was straightforward. It couldn't be any hard, just 2 examining histologically. 3 Q. Let's take a break. 4 -- RECESS AT 10:19 -- 5 -- UPON RESUMING AT 10:26 -- 6 BY MR. THOMAS: 7 Q. Doctor, going back to the images 8 on page 83 of your report, did you write a 9 pathology report of your findings for your review 10 of the histology? 11 A. Probably I did. Maybe I haven't 12 completed it yet. With the meshes, I'm slow, so I 13 could have completed the report, could have not. I 14 don't remember now. 15 Q. What's your practice for doing a 16 pathology report for a patient in the hospital who 17 is not involved in medical-legal? Do you turn that 18 around pretty quickly? 19 A. What do you mean is not involved 20 in medical-legal? 21 Q. I thought you told me this was not 22 a medical-legal case, this mesh that's on page 83 23 of your report? 24 A. That's correct. 25 Q. So, have you done a pathology</p> |

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| Page 70 | Page 72 |
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| <p>1 report for this patient based on your review of the 2 histology of her mesh? 3 A. Doesn't matter medical-legal or 4 not medical-legal, when I collect mesh specimens 5 because my work is done so slow, I think and it 6 takes me time. It has nothing to do with 7 medical-legal or not. The difference is mesh 8 versus no mesh. 9 Q. Have you prepared any -- have you 10 dictated anything related to the histology from the 11 mesh ex-plant that's depicted on page 83 of your 12 report? 13 MR. ORENT: Objection. 14 THE WITNESS: I don't remember. 15 BY MR. THOMAS: 16 Q. Have you written anything about 17 your review of the histology from the explanted 18 mesh that's based on page 83 of your report? 19 MR. ORENT: Objection. 20 THE WITNESS: As I said, I don't 21 remember. I've written something, because there 22 was a gross description at least there at the 23 beginning of the report. Maybe it's signed out, I 24 don't remember now. I use exactly the same format 25 for all mesh specimens litigation, non litigation.</p> | <p>1 Now we're getting into completely 2 different area and I said I'm not getting 3 comfortable in getting into confidential 4 information of a St. Michael's patient. 5 Q. I'm trying to figure out whether 6 anything in writing exists to your knowledge that 7 describes the findings you made based upon 8 histological review of this explanted mesh. 9 MR. ORENT: I think he's answered those 10 questions. I think he's gone far beyond his 11 comfort level. Let's move on. 12 MR. THOMAS: Are you instructing him 13 not to answer? 14 MR. ORENT: I'm not. However, if he 15 believes that he's confined by Canada's 16 confidentiality laws it's up to him in terms of his 17 knowledge, and what he can share as a doctor over a 18 patient who is not at issue in this lawsuit and not 19 put their medicals at issue. 20 THE WITNESS: As I said, I'm not 21 comfortable getting into further details. I think 22 it's inappropriate. This picture appeared in the 23 report because it was published. 24 BY MR. THOMAS: 25 Q. Doctor, on page 8 through 11 of</p> |
| Page 71 | Page 73 |
| <p>1 BY MR. THOMAS: 2 Q. I understand that. 3 A. And because there are so many 4 items I'm checking it takes me time and I don't 5 want to do it in a rush. 6 With cancer cases it is a different 7 story. I rush, I try to make sure diagnostic 8 process is not involved. In this case the mesh is 9 out already so there is no pressure. 10 Q. So to your knowledge, you don't 11 know whether the doctor or the patient had the 12 benefit of your pathological review of the 13 histology, correct? 14 A. I think I described it for the 15 physician. 16 Q. How did you describe it to her? 17 In writing or voicemail or person to person? 18 A. I don't remember now. I'm not 19 sure where we're going with this, this is 20 confidential, and I'm not comfortable getting into 21 confidential information of a St. Michael's 22 Hospital patient. 23 The paper has been published and the 24 picture made it in the report after the publication 25 was peer reviewed and accepted.</p> | <p>1 your report, you have a section titled 2 "Polypropylene Degradation and Review of Ethicon's 3 Internal Documents"? 4 A. That is correct. 5 Q. How did you determine what 6 documents to review from Ethicon? 7 A. I asked to send me anything which 8 was available pertinent to polypropylene 9 degradation, specifically if Ethicon scientists 10 performed testing using similar technology and 11 methodology, histology mainly. 12 Q. Did you rely on counsel to provide 13 to you the documents that you reviewed? 14 A. Yes. 15 Q. Did you produce for us on 16 Exhibit 4 all of the documents that you reviewed? 17 A. Yes, I did. 18 Q. Were there other documents that 19 plaintiff's counsel supplied to you that you did 20 not include on Exhibit 4? 21 A. Not to the best of my knowledge. 22 Q. All right. You also refer to 23 deposition testimony of Thomas Barbolt? 24 A. Yes. 25 Q. Is Dr. Barbolt's deposition on</p> |

19 (Pages 70 to 73)

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| <p style="text-align: right;">Page 74</p> <p>1 Exhibit 4?</p> <p>2 A. Yes, it is.</p> <p>3 Q. Do you remember how many days his</p> <p>4 deposition was?</p> <p>5 A. I think there were two days.</p> <p>6 Q. Did you read the whole thing?</p> <p>7 A. I read most of the deposition.</p> <p>8 Skimmed, I mean it's really long document.</p> <p>9 Q. Do you recall what his job was at</p> <p>10 Ethicon?</p> <p>11 A. I don't recall now.</p> <p>12 Q. Do you know what his training was?</p> <p>13 A. No.</p> <p>14 Q. Do you know what kind of testing</p> <p>15 Dr. Barbolt conducted while he was at Ethicon?</p> <p>16 A. I don't remember now.</p> <p>17 Q. Do you know whether he conducted</p> <p>18 any animal testing of mesh?</p> <p>19 A. I saw documents of animal testing,</p> <p>20 many documents. If he was part of all of them or</p> <p>21 some of them, I don't remember.</p> <p>22 Q. Do you know whether he conducted</p> <p>23 any tissue reaction studies?</p> <p>24 A. I don't remember that, no.</p> <p>25 Q. Do you know whether Dr. Barbolt</p> | <p style="text-align: right;">Page 76</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. What testing do you recall</p> <p>3 reviewing as a part of your review of the Ethicon</p> <p>4 documents in the case?</p> <p>5 A. As I said, I was focused mainly on</p> <p>6 histological examination but I also skimmed through</p> <p>7 the testing which was done using scanning electron</p> <p>8 microscopy and just regular light microscopy.</p> <p>9 Q. Did you have see any histological</p> <p>10 examination of what was described as cracked</p> <p>11 polypropylene sutures?</p> <p>12 A. Yes.</p> <p>13 Q. And what did you find in your</p> <p>14 review of the histological examination?</p> <p>15 A. I was really surprised. They</p> <p>16 found exactly what I found 30 years before I did.</p> <p>17 I did it independently; I didn't have those</p> <p>18 documents before. So I thought I was Columbus, but</p> <p>19 I guess I wasn't.</p> <p>20 Q. And you say they found exactly</p> <p>21 what you found?</p> <p>22 A. Yes, exactly the same. Even</p> <p>23 arrows were so much like mine.</p> <p>24 Q. What was it that they found which</p> <p>25 was exactly what you found?</p> |
| <p style="text-align: right;">Page 75</p> <p>1 compiled and reviewed testing on Prolene</p> <p>2 polypropylene from the 1960s to the present?</p> <p>3 A. As I said, there were many</p> <p>4 documents and it's hard for me to remember now.</p> <p>5 Q. Do you know -- strike that. Is it</p> <p>6 fair to understand that to the extent Dr. Barbolt</p> <p>7 presented any testing in his depositions you have</p> <p>8 not reviewed that testing?</p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: As I said, I was asking</p> <p>11 counsel to provide specific information, specific</p> <p>12 topics. So they provided this information and I</p> <p>13 received a number of documents.</p> <p>14 I specifically didn't even check</p> <p>15 whoever signed this, who were the names.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Did you review any of the testing</p> <p>18 Dr. Barbolt reviewed in his deposition?</p> <p>19 A. As I said --</p> <p>20 MR. ORENT: Objection.</p> <p>21 THE WITNESS: I don't remember the</p> <p>22 names. The only reason I remember his name because</p> <p>23 it was the only deposition I had specifically for</p> <p>24 that specific subject.</p> <p>25</p> | <p style="text-align: right;">Page 77</p> <p>1 A. There is a degradation bark and it</p> <p>2 retains histological dyes, and it also retains the</p> <p>3 granules of blue fibers. And they also used</p> <p>4 polarized light.</p> <p>5 I think you asked me earlier in the</p> <p>6 deposition who was using polarized light before.</p> <p>7 Your scientists were.</p> <p>8 Q. Is it your opinion that Ethicon</p> <p>9 conclusively found exactly what you found?</p> <p>10 A. Yes.</p> <p>11 Q. And that's based on the documents</p> <p>12 that have been provided to you?</p> <p>13 A. Yes.</p> <p>14 Q. Did you see any histological</p> <p>15 examination of the sutures that analyze to the</p> <p>16 extent to which it created any risk of harm to</p> <p>17 patients?</p> <p>18 A. I don't think I understand your</p> <p>19 question.</p> <p>20 Q. What don't you understand about</p> <p>21 it?</p> <p>22 MR. ORENT: Objection.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Let me start over again. During</p> <p>25 the course of your review of Ethicon documents, did</p> |

20 (Pages 74 to 77)

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| <p style="text-align: right;">Page 78</p> <p>1 you review any documents where Ethicon scientists</p> <p>2 reviewed histological slides of tissue samples</p> <p>3 containing mesh that was described as having</p> <p>4 cracks?</p> <p>5 A. Yes, I did.</p> <p>6 Q. And do you recall what the tissue</p> <p>7 reaction was that they described in those samples?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And what is that?</p> <p>10 A. It is the same thing which I saw,</p> <p>11 fibrosis foreign body reaction formation.</p> <p>12 Q. Do you know how the description</p> <p>13 they found in their documents compares to what the</p> <p>14 tissue reaction as described for Prolene sutures at</p> <p>15 the time that it was approved by the FDA in 1969?</p> <p>16 MR. ORENT: Objection.</p> <p>17 THE WITNESS: The documents I reviewed</p> <p>18 they were dated in '80s.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. I understand that.</p> <p>21 A. They had exactly the same</p> <p>22 description as earlier papers or papers after that.</p> <p>23 So I don't think there is any difference in any of</p> <p>24 the descriptions.</p> <p>25 Q. Okay.</p> | <p style="text-align: right;">Page 80</p> <p>1 THE WITNESS: I see it removed.</p> <p>2 Probably it's used for hernia mesh as well.</p> <p>3 Prolene or Marlex, I'm not sure. There are newer</p> <p>4 meshes coming on the market.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Does St. Michael's use Prolene</p> <p>7 polypropylene mesh for the treatment of stress</p> <p>8 urinary incontinence in TVT and TVT-O?</p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: I don't think so.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Do you know?</p> <p>13 A. Maybe in the past. Right now I</p> <p>14 just receive them when they're removed.</p> <p>15 They've been using them before. I</p> <p>16 don't know if they still using it right now.</p> <p>17 Q. Have you told St. Michael's to</p> <p>18 stop using Prolene polypropylene sutures?</p> <p>19 A. Not sutures. I talk to</p> <p>20 gynecologist. I show them what my research found,</p> <p>21 what I found, let them know, what's, what's my</p> <p>22 opinion about this.</p> <p>23 Q. Who did you talk to at St.</p> <p>24 Michael's about that?</p> <p>25 A. Our gynecologist.</p> |
| <p style="text-align: right;">Page 79</p> <p>1 A. Either at time of filing of the</p> <p>2 FDA application or after, it's all the same.</p> <p>3 Q. And the findings that they found</p> <p>4 in the '80s and the findings that they found</p> <p>5 earlier, and the findings that they reported later</p> <p>6 are just the same as yours are?</p> <p>7 A. Pretty much.</p> <p>8 Q. Okay. You say on page 9 of your</p> <p>9 report at the end of the first paragraph:</p> <p>10 "An important conclusion should</p> <p>11 be made that if chemical and</p> <p>12 physical properties have material</p> <p>13 change while it is in the body, it</p> <p>14 should not be used for permanent</p> <p>15 applications and for anatomical</p> <p>16 sites from which the devices cannot</p> <p>17 be safely removed."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes, you did.</p> <p>20 Q. Does St. Michael's use Prolene</p> <p>21 sutures?</p> <p>22 A. Yes, I understand they do.</p> <p>23 Q. Does St. Michael's use Prolene</p> <p>24 hernia mesh?</p> <p>25 MR. ORENT: Objection.</p> | <p style="text-align: right;">Page 81</p> <p>1 Q. I'm sorry?</p> <p>2 A. Our gynecologist.</p> <p>3 Q. And who is that?</p> <p>4 A. I don't think I can go there.</p> <p>5 Again, I'm not comfortable getting into specific</p> <p>6 information which is not relevant to my report.</p> <p>7 Q. What did you tell that person?</p> <p>8 A. I shared my research, what I</p> <p>9 shared in my papers.</p> <p>10 Q. Did you tell them that St.</p> <p>11 Michael's should not use Prolene polypropylene?</p> <p>12 A. I'm not making any guidelines.</p> <p>13 I'm not a regulating body. As a researcher I can</p> <p>14 share my opinion, my findings, with colleagues.</p> <p>15 And that's what I do in my publications and that's</p> <p>16 what I did in my personal conversations and</p> <p>17 personal contacts with St. Michael's physicians.</p> <p>18 Q. When did you have those</p> <p>19 conversations?</p> <p>20 A. Throughout. I've been involved in</p> <p>21 these meshes for the last year, maybe over a year,</p> <p>22 I don't remember now. First it was hernia</p> <p>23 surgeons, then gynecologists.</p> <p>24 Q. So you've spoken to hernia</p> <p>25 surgeons at St. Michael's about the use of</p> |

21 (Pages 78 to 81)

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| <p style="text-align: right;">Page 82</p> <p>1 polypropylene mesh?</p> <p>2 A. That's how it came, it came</p> <p>3 through hernia surgeons. The whole research</p> <p>4 project came through hernia surgeons.</p> <p>5 Q. Do you know whether hernia</p> <p>6 surgeons at St. Michael's are still using</p> <p>7 polypropylene mesh?</p> <p>8 A. Probably they do. But not all of</p> <p>9 them. Some of them do, some of them don't.</p> <p>10 Q. Do you know whether St. Michael's</p> <p>11 continues to use polypropylene mesh for the</p> <p>12 treatment of stress urinary incontinence?</p> <p>13 A. As I said, I know they've used it.</p> <p>14 I don't know if they're still using it right now as</p> <p>15 we speak.</p> <p>16 Q. Did you ever tell them as a</p> <p>17 scientist and pathologist that they should stop</p> <p>18 using Prolene polypropylene mesh because it was</p> <p>19 harming their patients?</p> <p>20 MR. ORENT: Objection.</p> <p>21 THE WITNESS: I described pathological</p> <p>22 findings and I disclosed everything I found in the</p> <p>23 specimens which were coming to me as part of St.</p> <p>24 Michael's Hospital and what I found during the</p> <p>25 course of my research. Yes, I did disclose all of</p> | <p style="text-align: right;">Page 84</p> <p>1 St. Michael's, isn't there?</p> <p>2 A. Yes, but not all of them are</p> <p>3 dealing with stress urinary incontinence. There is</p> <p>4 a degree of specialization. Some of them do it,</p> <p>5 sometimes some people specialize more in the field.</p> <p>6 Q. There's more than one hernia</p> <p>7 surgeon, isn't there?</p> <p>8 A. Yes, correct.</p> <p>9 Q. Is there someone over both of</p> <p>10 those specialties that can determine that the</p> <p>11 hospital should not use polypropylene sutures or</p> <p>12 mesh?</p> <p>13 A. I don't know if it can be done.</p> <p>14 Q. Have you ever made an effort to do</p> <p>15 that?</p> <p>16 A. To stop them?</p> <p>17 Q. (Nods).</p> <p>18 A. As I said, I don't know if it can</p> <p>19 be done.</p> <p>20 Q. Have you ever made an effort to</p> <p>21 stop St. Michael's Hospital from using Prolene</p> <p>22 sutures or Prolene mesh other than the</p> <p>23 conversations you had with a gynecologist and a</p> <p>24 hernia surgeon?</p> <p>25 A. No.</p> |
| <p style="text-align: right;">Page 83</p> <p>1 this.</p> <p>2 They are independent practitioners.</p> <p>3 They collect information from peer-reviewed</p> <p>4 studies. They see the evidence which is published.</p> <p>5 I'm one piece of the puzzle, one piece of the</p> <p>6 information.</p> <p>7 They make their own decision. They're</p> <p>8 licensed physicians and there are regulating bodies</p> <p>9 which give guidelines.</p> <p>10 Again, they are free to use my</p> <p>11 guidelines in my research or anything else and</p> <p>12 advise their patients what is the best course and</p> <p>13 what can be complications.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Who was the person at St.</p> <p>16 Michael's who makes the decision whether to use</p> <p>17 polypropylene mesh?</p> <p>18 A. Each individual physician makes</p> <p>19 own decisions after discussion with the patient.</p> <p>20 That's my understanding.</p> <p>21 I don't think there is any guiding body</p> <p>22 in specific hospital which can stop physicians from</p> <p>23 using specific device.</p> <p>24 Q. When you said you went to the</p> <p>25 gynecologist, there's more than one gynecologist at</p> | <p style="text-align: right;">Page 85</p> <p>1 Q. Thank you.</p> <p>2 What did Dr. Barbolt say about the</p> <p>3 clinical significance, if any, of surface cracks on</p> <p>4 polypropylene implanted in the dog study?</p> <p>5 A. I don't remember now.</p> <p>6 Q. What did Dr. Barbolt say about the</p> <p>7 molecular weight of the Prolene sutures implanted</p> <p>8 in the dog study after seven years?</p> <p>9 A. I don't remember now.</p> <p>10 Q. What did he say about the --</p> <p>11 strike that. What did Dr. Barbolt say about the</p> <p>12 physical properties of the Prolene sutures</p> <p>13 implanted in the dogs after seven years?</p> <p>14 MR. ORENT: Objection.</p> <p>15 THE WITNESS: I don't remember now.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Page 11 of your report. You talk</p> <p>18 about effect on the tissue, we're talking about</p> <p>19 pain -- sorry, I'm on the wrong page.</p> <p>20 It's on page 12, I'm sorry.</p> <p>21 A. Okay.</p> <p>22 Q. Page 12, it says:</p> <p>23 "It is important to note that</p> <p>24 in hernia surgery, chronic pain</p> <p>25 after mesh repair is a growing</p> |

22 (Pages 82 to 85)

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| <p style="text-align: right;">Page 86</p> <p>1 problem. Prophylactic neurectomy is 2 offered as a method to reduce 3 incidence of pain after mesh 4 repair." 5 What is a prophylactic neurectomy? 6 A. When you cut the nerves before you 7 put the mesh in anticipating the mesh is going to 8 cause pain. 9 Q. When you say cut the nerve, what 10 kind of nerve are you going to cut in the hernia 11 surgery? 12 A. There are three main nerves 13 branches: Genitofemoral, inguinal, um, some names, 14 um... 15 Q. Any other nerves as a part of the 16 hernia surgery? 17 A. There are three branches, which 18 can be identified visually. They are thicker 19 trunks. There is a variability between people, but 20 they're called triple neurectomy because in most 21 people there will be three branches supplying 22 innervation to the area. 23 Q. So tell me what is done and why 24 it's done in hernia surgery with prophylactic 25 neuroectomy?</p> | <p style="text-align: right;">Page 88</p> <p>1 So historically, first there were 2 meshes put in, and then more meshes put in, and 3 then more patients started coming back as chronic 4 pain, taking the mesh out was difficult, there was 5 large defect. 6 So somebody came up with the idea, 7 let's leave the mesh in but try to denervate the 8 area, either bury the nerves with some chemicals 9 like alcohol, or put nerve blocks, which was an 10 effective strategy. 11 You anesthetize the area, so the nerve 12 doesn't work for few weeks, and then the pain would 13 be gone. 14 And then somebody came up with this 15 idea of more permanent denervation, when the area 16 is anesthetized by cutting the nerve. 17 And then first surgeons try to do 18 neurectomy or transection of the nerve after mesh 19 repair, and after some experience they figure out 20 it's really hard to do to find the nerves from the 21 old scarred area. 22 So somebody offered, okay, if we 23 anticipate the pain developing from mesh, let's cut 24 the nerve before, when the area is clean and there 25 are no scarring or mesh in the area.</p> |
| <p style="text-align: right;">Page 87</p> <p>1 A. It depends. There's different 2 techniques. Either the branches can be cut in the 3 area, so there will be three branches identified 4 and transected, buried in muscle. The stumps will 5 be buried in muscle. 6 It could be also arthroscopic 7 techniques when they go and try and cut the nerve 8 trunks closer to the spinal cord. 9 Then I'm not sure if it will be three 10 branches, because if you go proximally it will be 11 less branches, they will all merge into larger 12 trunks. So you cannot call it triple neurectomy at 13 that level. 14 But the basic rule, we try to identify 15 supply innervation, either larger trunk or smaller 16 branches, transect them and bury the stump in the 17 muscles, so it doesn't form traumatic neuroma. 18 It's done because you want to denervate 19 the area where you anticipate the mesh is going to 20 cause pain. 21 Q. Why is it important to note the 22 prophylactic neurectomy in your report? 23 A. Because when chronic pain due to 24 mesh occurs, going back into the scarred area, 25 obstructed by the mesh, proved to be hard.</p> | <p style="text-align: right;">Page 89</p> <p>1 Q. Is that an accepted surgical 2 technique to do a nerve neurectomy prior to mesh 3 implantation? 4 A. Yes, it is. It's offered, it's 5 published and there are results. 6 Q. Is that a common occurrence with 7 mesh implantation? 8 MR. ORENT: Objection. Vague. 9 THE WITNESS: Depends on the surgeons. 10 Some surgeons believe in this and they do it. 11 Depends probably on the group of surgeons' practice 12 habits. 13 BY MR. THOMAS: 14 Q. Right above that section on the 15 prophylactic neurectomy, you discuss the mesh scar 16 complex and its "interlocking and 17 compartmentalizing nature". What is the 18 interlocking and compartmentalizing nature of the 19 mesh scar complex? 20 A. So if we look at the mesh, mesh is 21 a structure, three-dimensional structure made out 22 of mesh fibers or mesh filaments. 23 So filament of fiber, circles around, 24 loops around, and then it forms in pores, and in 25 these tissues. And each pore has 360 degrees of</p> |

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| <p style="text-align: right;">Page 90</p> <p>1 surrounding fibers, that's why it is a pore. 2 So it becomes a compartment. An area 3 which is surrounded by something or a physical 4 structure with volume inside, that is a 5 compartment. So the mesh introduces all these 6 micro compartments. 7 Q. There aren't walls around each of 8 these compartments, are there? 9 A. Yes, there are. Fibers, mesh 10 fibers, they form the walls of this compartment. 11 Q. But they don't totally encapsulate 12 -- strike that. 13 The compartment though, has an opening 14 on either side much like a screen, correct? 15 A. Yeah, more like a screen or a 16 tube. To a degree, because mesh is not completely 17 flat, it's a more of a three-dimensional. If you 18 go with microscopic level, it's three-dimensional. 19 So I would compare it with each pore as 20 a very complex irregular tube, more or less. 21 Q. My point is, instead of a 22 compartment it is a tube with openings on either 23 side? 24 A. A compartment is a tube. All 25 compartments in human body are tubes.</p> | <p style="text-align: right;">Page 92</p> <p>1 When it's used with scar it cannot so 2 that is lost. When it's incorporated in scar 3 tissue, the movement and bendability of fibers is 4 limited. 5 Q. Let me ask you a question here; I 6 don't mean to interrupt you. Is folding or curling 7 a necessary part of mesh stiffening? 8 A. No. It's one of the processes 9 which increases mesh stiffness if you compare it 10 with the flat product. 11 Q. So you can have, as far as you're 12 concerned, mesh stiffening if the mesh does not 13 fold or curl? 14 A. Then other mechanisms will set in. 15 Q. But the first one deals with 16 folding, curling and then the scar that you just 17 described? 18 A. Yes. 19 Q. I didn't mean to interrupt you. 20 Is there anything else you wanted to say about that 21 mechanism? 22 A. And then slowly over the years, 23 the degradation layer will start building up and we 24 know it's brittle. Like any other plastic, we see 25 over time it starts cracking. It becomes harder</p> |
| <p style="text-align: right;">Page 91</p> <p>1 Q. That has an opening on either 2 side? 3 A. Yes, that's how they are in the 4 body. If we talk about tunnel syndromes in the 5 hand or in the chest, all these compartments form a 6 tube. 7 And the tube lets nerves and blood 8 vessels through and if compartment syndrome occurs, 9 it compromises the nerves in the vessel, in the 10 tube-like structure. 11 Q. Doctor, in your report you 12 discussed the concept of mesh stiffening? 13 A. Yes, I did. 14 Q. Please tell me how mesh stiffens? 15 A. Immediately after placement, it 16 can fold and curve. So two layers or three layers 17 of mesh is different than one layer. So this is 18 initial step, if it folds or curls or wrinkles 19 immediately after placement. 20 Then next step which will increase 21 stiffness of the structure is scar encapsulation. 22 So scar immobilizes the fibers in the structures so 23 they can not move inside the elasticity of the 24 meshes, mainly because of the bending ability of 25 the fibers and movement within the structure.</p> | <p style="text-align: right;">Page 93</p> <p>1 and less flexible and it breaks. 2 Q. The degradation layer you 3 described is four to five microns? 4 A. It depends. It depends how long 5 it's been in the body. 6 Q. Is four to five microns about the 7 largest you've seen? 8 A. No, I've seen up to seven or 9 eight. Depends on the type of mesh, I guess -- 10 Q. Well, Prolene polypropylene, what 11 is the largest you've seen? 12 A. It's hard to say because it's for 13 -- currently that mesh is -- 80 percent of the time 14 I don't actually know what the product is. 15 Q. 80 percent of the time you don't 16 know what the product is? 17 A. Yes. 18 Q. And the reason why I ask is, in 19 all the reports I've seen, I've never seen you give 20 an opinion that is greater than five microns to a 21 Prolene mesh? 22 A. That's just happened with any 23 litigation process, but I have over 300 meshes in 24 my office. 25 I'm just telling you the thickest bark</p> |

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| <p style="text-align: right;">Page 94</p> <p>1 as far as I remember was up to seven, probably just 2 over seven microns thick. 3 And I think it was a hernia mesh and 4 for hernia meshes, when they've been in the body 5 for like 12 or 14 years, it's very difficult to 6 trace what type of mesh was put in. 7 Q. Your best recollection insofar as 8 you're dealing with Prolene mesh for the treatment 9 of stress urinary incontinence, the largest you've 10 seen is five microns, correct? 11 MR. ORENT: Objection. 12 THE WITNESS: Probably six, I don't 13 remember now. 14 BY MR. THOMAS: 15 Q. This bark, as you've described it, 16 by definition is cracking? 17 A. Yes. 18 Q. And when you get past the bark 19 layer the interior of the polypropylene as best as 20 you can tell is unaffected? 21 A. Yes. 22 Q. Okay. 23 A. The core of the fibers remains, at 24 least, the same by my methods. 25 Q. And by your methods, as far as you</p> | <p style="text-align: right;">Page 96</p> <p>1 MR. ORENT: Objection. 2 THE WITNESS: For litigation cases? 3 Meshes come in formalin, that is correct. But in 4 St. Michael's Hospital, when they receive mesh, as 5 I mentioned, everybody knows I'm the mesh guy. 6 They call me when they receive a mesh, sometimes I 7 receive them fresh. 8 BY MR. THOMAS: 9 Q. Do you have any documents, images 10 or any other information about meshes that you've 11 received fresh, without formalin, that show folding 12 or curling? 13 MR. ORENT: Objection to form. 14 THE WITNESS: I describe them when I 15 receive them. But again, we're going to the St. 16 Michael's Hospital patients and I don't want to go 17 there. I'm not comfortable discussing this 18 confidential information. 19 BY MR. THOMAS: 20 Q. Okay. 21 A. Probably took some pictures at 22 some time. 23 Q. You have not produced those 24 pictures to us? 25 A. They're not in the report.</p> |
| <p style="text-align: right;">Page 95</p> <p>1 can tell, past the five microns or so, the physical 2 properties of the polypropylene remain the same, 3 true? 4 MR. ORENT: Objection. 5 THE WITNESS: By my methods, yes. 6 BY MR. THOMAS: 7 Q. Have you described -- you've 8 described two ways that you believe that mesh 9 becomes stiff. 10 Are there any other ways that you 11 believe mesh becomes stiff in the body? 12 A. Three. So multi layering, scar 13 encapsulation and then degradation. No, I don't 14 know any other mechanism for stiffening. 15 Q. And the way that you're able to 16 identify multi layering is when you analyze the 17 mesh after it's been sent to you in formalin from 18 the surgeon, correct? 19 A. As I said, sometimes I receive 20 meshes fresh in saline or not just -- and I see 21 it's folded already. 22 Q. The only polypropylene meshes that 23 you've given us, other than the one that you've 24 given us limited information about, come to you in 25 formalin, correct?</p> | <p style="text-align: right;">Page 97</p> <p>1 They're confidential information and I took them 2 because in the course of my work as a pathologist 3 at St. Michael's. 4 Q. Do you have any information about 5 the incidents of folding or curling in mesh 6 implanted -- in Prolene mesh implanted for the 7 treatment of stress urinary incontinence? 8 A. For stress urinary incontinence, 9 the degree of curling is visible in most of the 10 cases. 11 Q. More than half? 12 A. I would say more than half. 13 Again, it depends. Sometimes one piece is curled, 14 the other one is completely flat. 15 Q. And again, these are cases where 16 you've received the mesh in formalin? 17 A. Yes. But I mean we're talking 18 about curling, not curling on the whole specimen. 19 We're talking about curling as it sits in scar 20 tissue. 21 So whatever curling I'm assessing as is 22 significant is on that, that which can -- which is 23 immobilized by scar tissue. 24 So I'm not talking about curling which 25 occurs secondary to fixation. I'm talking about</p> |

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| <p style="text-align: right;">Page 98</p> <p>1 curling which occurred in the body. I'm able to</p> <p>2 distinguish between one and the other.</p> <p>3 Q. How?</p> <p>4 A. I just said. If it's curled and</p> <p>5 it's completely surrounded, integrated in scar</p> <p>6 tissue in curled shape, it occurred in the body.</p> <p>7 If the entire specimen is curled</p> <p>8 together with scar, that could have been an</p> <p>9 artifact. So I immediately disregard the shape or</p> <p>10 the formation which occurred as an artifact.</p> <p>11 Q. Let's go to page 19 of your</p> <p>12 report, please.</p> <p>13 A. Um-hum.</p> <p>14 Q. I'm going to refer you back to</p> <p>15 page 14, because I think that that's the commentary</p> <p>16 that you have on that. So you've got 19, which is</p> <p>17 the images, and page 14 is the text.</p> <p>18 A. Yes.</p> <p>19 Q. Okay. As you look at page 19,</p> <p>20 Figure Set 1a is described as:</p> <p>21 "A foreign body inflammatory</p> <p>22 reaction H&E, 40X images</p> <p>23 consolidated cases."</p> <p>24 What are you showing here?</p> <p>25 A. Foreign body type inflammatory</p> | <p style="text-align: right;">Page 100</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. The images on the left show that</p> <p>3 the polypropylene was removed as part of the</p> <p>4 microtoming process; correct?</p> <p>5 A. Could you repeat that question.</p> <p>6 Q. I'm looking at the figures on the</p> <p>7 left, which show the white images, compared to the</p> <p>8 right, which show the yellow.</p> <p>9 And on the left it shows that the</p> <p>10 polypropylene that used to be where the white is</p> <p>11 has been removed as a part of the microtoming</p> <p>12 process; correct?</p> <p>13 A. No, actually, there might be all</p> <p>14 of them present there. They're just clear;</p> <p>15 polypropylene is clear. If it is not degraded,</p> <p>16 it's completely clear.</p> <p>17 If the fibers were blue fibers, they</p> <p>18 would be visible. If it's clear fiber they would</p> <p>19 not.</p> <p>20 So technically, looking at these</p> <p>21 images, we cannot say which hole is the actual MTM,</p> <p>22 and which sort of appear in holes, still contain</p> <p>23 polypropylene. You would need polarized light to</p> <p>24 see that.</p> <p>25 Q. So what can you tell me about the</p> |
| <p style="text-align: right;">Page 99</p> <p>1 reaction.</p> <p>2 Q. Is there anything unusual about</p> <p>3 this foreign body reaction?</p> <p>4 A. What do you mean unusual?</p> <p>5 Q. Is there anything remarkable about</p> <p>6 it? There's a foreign body reaction anytime you</p> <p>7 have an implant, correct?</p> <p>8 A. Then usually it's not normal</p> <p>9 tissue. Normally there shouldn't be any</p> <p>10 inflammation in the tissue.</p> <p>11 Q. Okay. And so would there be</p> <p>12 inflammation regardless of what kind of foreign</p> <p>13 body is placed in there?</p> <p>14 A. Yes, because having a foreign body</p> <p>15 in the body is not normal thing.</p> <p>16 Q. And so is it fair to say that</p> <p>17 Figure Set 1a describes a typical foreign body</p> <p>18 reaction to implanted materials?</p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: I wouldn't say typical,</p> <p>21 although you can use that word. I would say</p> <p>22 non-specific reaction to a foreign body. The body</p> <p>23 is trying to destroy the foreign body because it's</p> <p>24 a noxious stimulus, a noxious or damaging object.</p> <p>25</p> | <p style="text-align: right;">Page 101</p> <p>1 part of the mesh that we're seeing in Figure 1a?</p> <p>2 A. Specifically, I don't -- do you</p> <p>3 want me to discuss a specific feature?</p> <p>4 Q. For example, you don't have a</p> <p>5 clean cut where you're looking at a perfectly round</p> <p>6 portion of the mesh, correct?</p> <p>7 MR. ORENT: Objection to form, to the</p> <p>8 use of the term "clean cut".</p> <p>9 THE WITNESS: Some of them are closer</p> <p>10 to perpendicular orientation. Some of them are</p> <p>11 angled.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Okay. For example, when you have</p> <p>14 a microtoming process and you pull the knife across</p> <p>15 the histological slide, sometimes you will create</p> <p>16 an artifact by pulling the tissue away from the</p> <p>17 polypropylene, correct?</p> <p>18 A. Yes, because polypropylene is</p> <p>19 harder than tissue, you can damage tissue during</p> <p>20 cutting.</p> <p>21 Q. And you can't tell if you look at</p> <p>22 set 1a whether the polypropylene is there or not;</p> <p>23 true?</p> <p>24 A. Yes, that's true.</p> <p>25 Q. You can't tell by looking at the</p> |

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| <p>1 figures in set 1a whether those are the actual size</p> <p>2 of the hole that was occupied by the polypropylene,</p> <p>3 and whether that is an artifact from microtoming?</p> <p>4 A. That I can tell you because</p> <p>5 artifact from microtoming looks completely</p> <p>6 different. These are holes from fibers.</p> <p>7 Q. Completely?</p> <p>8 A. For these specific holes?</p> <p>9 Q. How can you tell the difference?</p> <p>10 A. Well, you have to work as I</p> <p>11 pathologist for so many years and then you can</p> <p>12 tell.</p> <p>13 But generally, how we go for that</p> <p>14 specific feature, it would be shape, rounded shape,</p> <p>15 oblique, assuming, if we look at this image here --</p> <p>16 if you want me to point, circle.</p> <p>17 Q. I'll give you a red pen -- let's</p> <p>18 give you a blue pen. That will show up better.</p> <p>19 A. Assuming if we see this tissue,</p> <p>20 this specific, this is displaced. So when the</p> <p>21 fiber was not cut, it probably had different</p> <p>22 position, different orientation. Because it's</p> <p>23 misplaced, it doesn't completely circle here.</p> <p>24 Q. Is that an artifact from the</p> <p>25 microtoming process?</p> | <p>1 the mesh fiber.</p> <p>2 Q. Okay. Let's go now to the next</p> <p>3 page, page 20. Anything else remarkable about that</p> <p>4 page, page 19?</p> <p>5 A. It depends what you want me to</p> <p>6 describe.</p> <p>7 Q. Well, I've seen you testify</p> <p>8 before. And you put these images up on the screen</p> <p>9 and you tell the jury what you think is remarkable</p> <p>10 about them?</p> <p>11 A. Do you want me to go through this</p> <p>12 description?</p> <p>13 Q. Do you have anything other than a</p> <p>14 foreign body reaction, as depicted in the tissue,</p> <p>15 is there anything other than that that's remarkable</p> <p>16 about the images on 19?</p> <p>17 A. This picture is actually good in</p> <p>18 terms of it shows this layering.</p> <p>19 So the fibers are surrounded by this</p> <p>20 dense foreign body type inflammation, and then the</p> <p>21 inflammation is actually encapsulated by dense scar</p> <p>22 on the outside, so this very dense pink area is a</p> <p>23 scar. So it goes on the outside of the</p> <p>24 inflammation.</p> <p>25 And then beyond the scar plate, here is</p> |
| Page 103 | Page 105 |
| <p>1 A. To a degree.</p> <p>2 Q. Okay.</p> <p>3 A. Now, see this empty space here?</p> <p>4 Q. Mark that A. Mark the first one</p> <p>5 A, and the next one B, so the record is clear what</p> <p>6 you've just done.</p> <p>7 A. (Witness complies).</p> <p>8 Q. This one will be A. That's the</p> <p>9 one you've discussed first. The other one you're</p> <p>10 discussing now is B.</p> <p>11 A. So this circle labelled A moved</p> <p>12 during microtomy. It was within the fibers and now</p> <p>13 it moved, it changed position slightly.</p> <p>14 The area B appears empty, but it was</p> <p>15 occupied in vivo, and this is an artifact. Another</p> <p>16 artifact here is artifact C, which is tissue</p> <p>17 retraction. Now, if we --</p> <p>18 Q. And those are all caused by the</p> <p>19 microtoming process?</p> <p>20 A. No. Different combination of</p> <p>21 factors which cause all of this.</p> <p>22 Now, if we look at the entire opening</p> <p>23 marked as D, is perfect round shape, no tissue is</p> <p>24 displaced. So this would be as close as it gets to</p> <p>25 the area which is occupied by a cross-section of</p> | <p>1 the transition into normal lighter tissue not as</p> <p>2 densely scarred or densely collagenized.</p> <p>3 So this picture is a good example of</p> <p>4 showing this multilayering, sort of onion skin</p> <p>5 around the mesh fibers.</p> <p>6 Q. Anything else?</p> <p>7 A. No.</p> <p>8 Q. Let's go to page 20 now.</p> <p>9 A. Now, I have the mark coming</p> <p>10 through. Should I use a pen?</p> <p>11 Q. We'll do that next time, we'll</p> <p>12 take that away.</p> <p>13 Now on page 20, again, this is an image</p> <p>14 from the consolidated cases?</p> <p>15 A. That's correct.</p> <p>16 Q. And as you look in the top on 1b,</p> <p>17 you see blue. And that is polypropylene mesh.</p> <p>18 A. Yeah, that's a cross-section of a</p> <p>19 blue polypropylene fiber.</p> <p>20 Q. And it looks like it's been folded</p> <p>21 as a part of the microtoming process; is that fair?</p> <p>22 A. It's not microtoming process; it</p> <p>23 folds, curls. Polypropylene just tends to curl.</p> <p>24 Q. But this is a four-micron thick</p> <p>25 slice of polypropylene, correct?</p> |

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| <p>1 A. Then it curls up like this. Some</p> <p>2 of them just stay flat. Some of them curl up.</p> <p>3 Q. But this is an artifact of the</p> <p>4 sample preparation process?</p> <p>5 A. Curling? Yes.</p> <p>6 Q. So the curling of the blue</p> <p>7 polypropylene in set 1b on page 20 is an artifact</p> <p>8 of the sample preparation process?</p> <p>9 A. That's correct.</p> <p>10 Q. All right?</p> <p>11 A. The exact shape of that slice is</p> <p>12 better to be estimated by the tissue which</p> <p>13 surrounds it because tissue didn't curl, didn't</p> <p>14 move much. There is more movement of the</p> <p>15 polypropylene slices.</p> <p>16 Q. What does that mean? I don't</p> <p>17 understand.</p> <p>18 A. Well, see, when the tissue is cut</p> <p>19 it doesn't curl, it doesn't wrinkle most of the</p> <p>20 time because of the technology of the slides and</p> <p>21 knives. Everything was designed to keep it flat.</p> <p>22 So over the years, over the hundred</p> <p>23 years we learned how to keep it flat. With</p> <p>24 polypropylene, because it is a different material,</p> <p>25 doesn't stick. The histological slides don't hold</p> | <p>1 slide comes from the set of 22 patients that you</p> <p>2 received from Dr. Kreutzer?</p> <p>3 MR. ORENT: Objection.</p> <p>4 THE WITNESS: My recollection is it was</p> <p>5 later, one of the later cases.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Do you know which one it is?</p> <p>8 A. I can probably trace it but...</p> <p>9 Q. Is it a medical-legal case?</p> <p>10 A. I think so, but again it would be</p> <p>11 hard for me -- just what I recall, it is a TVT that</p> <p>12 I kept track quite well, TVT or TVT-O.</p> <p>13 Q. If I asked you to, could you tell</p> <p>14 me where it came from?</p> <p>15 A. I can make an effort to figure it</p> <p>16 out.</p> <p>17 Q. Okay.</p> <p>18 A. If I can't, I can't.</p> <p>19 Q. I'm going to want to know where</p> <p>20 all these came from. That's what we asked for in</p> <p>21 advance and I understand we don't have it today?</p> <p>22 A. I never had the purpose to trace</p> <p>23 individual cases unless it's for a specific -- the</p> <p>24 report is prepared for a specific patient.</p> <p>25 Q. Okay.</p> |
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| <p>1 it as well so it's not firmly attached.</p> <p>2 So, when it's cut initially, it may</p> <p>3 stay flat. But then after drying and some chemical</p> <p>4 treatment, starts curling up, while tissue stays</p> <p>5 flat.</p> <p>6 Q. Okay.</p> <p>7 A. Curling up or moving, I mean curls</p> <p>8 up, lifts up, and then starts floating around.</p> <p>9 Q. What are you going to say at trial</p> <p>10 about Figure Set 1b on page 20?</p> <p>11 A. Just an example of foreign body</p> <p>12 type inflammatory reaction.</p> <p>13 Q. Okay. Let's go to page 21.</p> <p>14 A. Yes.</p> <p>15 Q. Page 21 is Figure Set 1c:</p> <p>16 "Foreign body inflammatory</p> <p>17 reaction, H&E 40X, image of</p> <p>18 additional TVT cases."</p> <p>19 Now, I think you told us before that</p> <p>20 these are previous TVT and TVT-O cases?</p> <p>21 A. Yes.</p> <p>22 Q. Do you know whether this is a TVT</p> <p>23 or a TVT-O?</p> <p>24 A. No.</p> <p>25 Q. Can you tell me today whether this</p> | <p>1 A. Because of it wasn't my purpose.</p> <p>2 My purpose was to collect information and</p> <p>3 photographs for TVT or TVT-O as device. That's why</p> <p>4 I have difficulty tracing all of them back. Some</p> <p>5 of them can be traced; some of them cannot.</p> <p>6 Q. If you look at Figure Set 1c, top</p> <p>7 left, again, you see the blue polypropylene,</p> <p>8 correct?</p> <p>9 A. Yes, I do. And the other hole</p> <p>10 above it may still contain polypropylene but it's</p> <p>11 clear because the way it's done two fibers are</p> <p>12 combined together.</p> <p>13 One filament is blue, one filament is</p> <p>14 clear. And they go through the knitting product</p> <p>15 together, this pair.</p> <p>16 Q. Does the fact that the hole that</p> <p>17 you just identified above the presence of blue</p> <p>18 polypropylene has an irregular shape, does that</p> <p>19 impact your opinion as to whether the polypropylene</p> <p>20 is present or not?</p> <p>21 A. Not irregular. It's more regular</p> <p>22 curvilinear shape, and there is inflammation around</p> <p>23 it, so there are several features which tell me</p> <p>24 that this is space where polypropylene either still</p> <p>25 is or used to be.</p> |

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| <p>1 If I had polarized light or if I had</p> <p>2 microscope right now and it would be in the</p> <p>3 microscope, I could flip polarized light and see.</p> <p>4 Q. Now, is that tissue that is in</p> <p>5 that large white area above the polypropylene?</p> <p>6 A. It is a small fragment of tissue.</p> <p>7 Q. Is that part of a microtoming</p> <p>8 artifact?</p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: Microtomy or processing,</p> <p>11 it's hard to say, but it's an artifact. It's</p> <p>12 displaced.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. As you look down to the piece of</p> <p>15 polypropylene in set 1c, on the top of that blue</p> <p>16 portion it appears to be some tissue?</p> <p>17 A. Yes.</p> <p>18 Q. And that tissue looks to fit right</p> <p>19 into the tissue above it?</p> <p>20 A. That's correct.</p> <p>21 Q. So that's pulled away from the</p> <p>22 tissue as a part of the microtoming process,</p> <p>23 correct?</p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: You have good eyes.</p> | <p>1 A. Yes, sometimes I do that.</p> <p>2 Q. Okay. Anything else remarkable</p> <p>3 about the figures on page 21?</p> <p>4 A. No.</p> <p>5 Q. Let's go to page 22, Figure Set</p> <p>6 2a. Again, this is images of additional TVT cases.</p> <p>7 And these would be cases that were not part of the</p> <p>8 consolidated group that you've just reviewed,</p> <p>9 correct?</p> <p>10 A. That is correct.</p> <p>11 Q. And can you tell me by looking at</p> <p>12 this whether it was part of the set of cases that</p> <p>13 you received from Dr. Kreutzer?</p> <p>14 A. No, that was later case.</p> <p>15 Q. How can you tell me that? How do</p> <p>16 you know that?</p> <p>17 A. Quality of the picture. I see it</p> <p>18 was not taken with the camera that I had at the</p> <p>19 time that I received the, those specimens.</p> <p>20 Q. Was this taken from an active</p> <p>21 medical-legal case involving Ethicon?</p> <p>22 MR. ORENT: Objection to the form.</p> <p>23 THE WITNESS: I don't remember. Most</p> <p>24 likely it is.</p> <p>25</p> |
| Page 111 | Page 113 |
| <p>1 BY MR. THOMAS:</p> <p>2 Q. Why don't I see any bark on that</p> <p>3 polypropylene?</p> <p>4 A. Two reasons. Not enough</p> <p>5 resolution of the picture, and second, not in</p> <p>6 focus.</p> <p>7 Q. And do you know how long this mesh</p> <p>8 was implanted in the person?</p> <p>9 A. No, I don't remember.</p> <p>10 Q. But you have those records?</p> <p>11 A. Most likely. But again, some</p> <p>12 patient samples came without much records. Most of</p> <p>13 the samples I received had implantation dates.</p> <p>14 Q. So what is remarkable about the</p> <p>15 slides in Figure Set 1c which you'll talk to the</p> <p>16 jury about?</p> <p>17 A. It shows a blue fiber. It shows</p> <p>18 that some of the fibers are blue, but otherwise it</p> <p>19 shows exactly the same feature as before.</p> <p>20 It's kind of onion skin mesh fiber</p> <p>21 covered by inflammation, and then outside of that</p> <p>22 everything is encapsulated in scar tissue.</p> <p>23 Q. And the scar tissue would be</p> <p>24 reflected in your notations in the ones on the</p> <p>25 right?</p> | <p>1 BY MR. THOMAS:</p> <p>2 Q. But you can't tell me today what</p> <p>3 it might be?</p> <p>4 A. It's hard to say.</p> <p>5 Q. And what is remarkable about the</p> <p>6 image in Figure Set 2a on page 22 for purposes of</p> <p>7 the jury?</p> <p>8 A. Can I have a pen?</p> <p>9 Q. I'll give you a blue pen.</p> <p>10 A. Remember, earlier you asked me</p> <p>11 about why you cannot see bark? Now you can see the</p> <p>12 bark, so this is the bark. Right there.</p> <p>13 Q. What you've indicated is on the</p> <p>14 left?</p> <p>15 A. This is the bark right there.</p> <p>16 This is the bark right there.</p> <p>17 Q. Now are you assuming for purposes</p> <p>18 of that statement that polypropylene is still</p> <p>19 present in that slide?</p> <p>20 A. Well, degraded part of the</p> <p>21 polypropylene is still present for sure, because I</p> <p>22 can see it stained. If the core remains unlocked,</p> <p>23 there's a different question. In this area, most</p> <p>24 likely it is.</p> <p>25 Q. You say most likely it is?</p> |

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| <p>1 A. Because this bark layer is free in 2 the space, and doesn't happen that often. Because 3 if it was free in this area, it would flow all the 4 way. So the way it remains in the tissue it 5 remains attached to tissue. 6 So the bark which is firmly attached to 7 tissue like in this area is most likely detached. 8 So there is no fiber core in this area. But in 9 this specific area, I suspect the core of the fiber 10 is still there. 11 Q. Let me do something so the record 12 is clear. 13 You've made some arrows on Figure 2 A, 14 on the upper image, and there's two arrows on the 15 upper left-hand portion and you suggest that 16 indicates bark -- you suggest that indicates bark, 17 correct? 18 A. I didn't suggest. I just pointed 19 where it is. 20 Q. Okay, fine. And then down in the 21 lower right-hand corner, you've drawn several 22 diagonal lines in addition to two arrows. 23 The two arrows indicate bark, as you 24 understand it, and you believe that the diagonal 25 lines represent polypropylene which is present in</p> | <p>1 case, you have the report. 2 BY MR. THOMAS: 3 Q. Are you familiar with whole slide 4 imaging? 5 A. Yes, I am. 6 Q. Do you do whole slide imaging of 7 these cases? 8 A. Yes, I do. 9 Q. So you have -- 10 A. Not for all of them. For some 11 cases, especially the later ones. 12 Q. Okay. And who maintains your 13 whole slide imaging equipment; who has that? St. 14 Michael's? 15 A. Yes, St. Michael's. It's standard 16 equipment. 17 Q. Do you have to pay St. Michael's 18 for use of the whole slide imaging equipment? 19 A. No. 20 Q. Okay. 21 A. It's free for researchers. 22 Q. What kind of machine do they have? 23 A. Aperio. 24 Q. So, you could supply to us digital 25 images of the slides that you have on whole slide</p> |
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| <p>1 the slide, correct? 2 A. Most likely. 3 Q. Okay. Now, we requested that all 4 of the slides that were used in your report be 5 forwarded to our pathologist for their review. 6 Was this slide forwarded to them, to 7 your knowledge? 8 MR. ORENT: Objection. 9 THE WITNESS: No, it's an additional 10 case. 11 BY MR. THOMAS: 12 Q. Okay. 13 MR. ORENT: By the way, just for the 14 record, we have not received any slides from your 15 pathologist either and we have requested that 16 repeatedly. 17 MR. THOMAS: We don't have any to give 18 you. We're working from the same set of slides. 19 MR. ORENT: So you're using the 20 plaintiff's stained slides -- 21 MR. THOMAS: So far we have. We figure 22 it's better off using one set of slides. And to 23 the extent we make any, you will have them 24 promptly. 25 THE WITNESS: If it was a litigation</p> | <p>1 imaging, correct? 2 A. As long as you're entitled to 3 receive material or information about the case. 4 Q. Okay. What else is remarkable 5 about Figure Set 2a on page 22? 6 A. Oh, it is a very nice example, 7 again of this layering, onion skinning. 8 The mesh fibers are surrounded by halo 9 of foreign body reaction and everything is encased 10 in solid scar plate. 11 And then normal tissue is beyond the 12 solid scar plate so it is a good example of how it 13 happens. 14 Q. And in terms of -- you've told me 15 that on the upper left of the area where you had 16 the arrows, there's likely not polypropylene but in 17 the lower right there likely is polypropylene? 18 A. Yes. 19 Q. How about in the white area to the 20 right where you've written; can you tell whether 21 polypropylene is present or not? 22 A. Not without polarized light. 23 MR. ORENT: Counsel, we've been going 24 about another hour. Shall we take a short break? 25 MR. THOMAS: Good time, yes.</p> |

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|---|---|
| <p>1 -- RECESS AT 11:27 --</p> <p>2 -- UPON RESUMING AT 11:44 --</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. Doctor, going back to image 2a on</p> <p>5 page 22 of your report, you described this scar</p> <p>6 area in your testimony, and then showed how the</p> <p>7 scar then changed to normal tissue, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. How thick is the area between what</p> <p>10 you show to be the polypropylene mesh and the scar</p> <p>11 to the normal tissue? How thick is that area</p> <p>12 between the polypropylene and the normal tissue?</p> <p>13 A. You mean in this specific image or</p> <p>14 in general?</p> <p>15 Q. In this image.</p> <p>16 A. It depends on which part of the</p> <p>17 mesh. The thinnest part is within the hundred</p> <p>18 microns. The thickest part can be as thick as</p> <p>19 couple of millimeters, if we measure the whole</p> <p>20 thing like this.</p> <p>21 Q. And just for the record, when you</p> <p>22 say within a hundred microns, you're referring to</p> <p>23 the area on the left side of the lower image in the</p> <p>24 yellow, through the scar to the normal tissue. And</p> <p>25 when you're referring to the couple of millimeters,</p> | <p>1 Where does this come from?</p> <p>2 A. It came from, if I remember</p> <p>3 correctly, Edwards case. If I remember correctly.</p> <p>4 Q. What is it about this that makes</p> <p>5 you think it's the Edwards case?</p> <p>6 A. It is an old photograph.</p> <p>7 Q. And in the top, on the right-hand</p> <p>8 side of the image, it looks like a piece of blue</p> <p>9 polypropylene that's displaced in its location; is</p> <p>10 that fair?</p> <p>11 A. Slightly displaced, most of it</p> <p>12 sits right there, it was in vivo.</p> <p>13 Q. The other blue pieces that appear</p> <p>14 there other than the -- why don't you just mark</p> <p>15 that with an "X" for me so it's clear what we're</p> <p>16 talking about.</p> <p>17 A. (Witness complies).</p> <p>18 Q. There are other blue pieces</p> <p>19 throughout that image, is that polypropylene or is</p> <p>20 that stain?</p> <p>21 A. You mean the blue areas here?</p> <p>22 Q. Yes.</p> <p>23 A. Some of it is probably displaced</p> <p>24 polypropylene, it's hard to say because of the</p> <p>25 resolution. It could just be inflammation because</p> |
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| <p>1 you were referring to normal tissue to normal</p> <p>2 tissue in between the two mesh fibers; is that</p> <p>3 fair?</p> <p>4 MR. ORENT: Objection.</p> <p>5 THE WITNESS: That's correct.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. And similarly, down below on the</p> <p>8 lower left, where you show the polypropylene mesh,</p> <p>9 you show scar and then you do show normal tissue;</p> <p>10 how far is it from the polypropylene to the normal</p> <p>11 tissue; how wide is the scar band?</p> <p>12 A. The same, within 100 microns.</p> <p>13 Sometimes you have normal tissue pushing into the</p> <p>14 pores, sometimes not. Sometimes the scar plate is</p> <p>15 within a hundred microns -- I mean, the scar</p> <p>16 capsule. Sometimes it goes to the millimeters,</p> <p>17 three, four millimeters, it depends.</p> <p>18 Q. Okay. Anything else remarkable</p> <p>19 about the images on page 22?</p> <p>20 A. No, we discussed everything, I</p> <p>21 think.</p> <p>22 MR. ORENT: Objection.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Let's go to page 23 please, Figure</p> <p>25 Set 2b. Let's talk about this a little bit.</p> | <p>1 there is a weird color coming into the pictures.</p> <p>2 Q. If the blue that appears there is</p> <p>3 in fact displaced polypropylene, then that's part</p> <p>4 of the microtoming artifact; is that fair?</p> <p>5 A. Yes, that's fair.</p> <p>6 Q. All right.</p> <p>7 A. Anywhere where cross-section of</p> <p>8 the fiber overlaps with tissue, is a displacement.</p> <p>9 Q. All right. And you title this,</p> <p>10 "Fibrous Bridging and Scar Encapsulation". And</p> <p>11 it's four times power. What does this show?</p> <p>12 A. All pores in this section of the</p> <p>13 mesh are filled with scar tissue. So normal tissue</p> <p>14 is beyond the scar plate, and all the pores are in</p> <p>15 the spaces in between, and mesh walls are filled</p> <p>16 with scar tissue.</p> <p>17 Q. Okay. The magnification of the</p> <p>18 image on the prior page is five times this</p> <p>19 magnification, correct?</p> <p>20 A. About, yes.</p> <p>21 Q. Okay. And can you tell me by</p> <p>22 looking at the image on page 23 in the cluster of</p> <p>23 four circles, how close it is from the</p> <p>24 polypropylene across the scar tissue to the normal</p> <p>25 tissue?</p> |

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| <p>1 A. In this area?</p> <p>2 Q. Yes.</p> <p>3 A. It would be within the 100 microns</p> <p>4 or so.</p> <p>5 Q. Mark that -- good.</p> <p>6 A. (Witness complies).</p> <p>7 In this case, it's thicker, could be as</p> <p>8 thick as 200 microns.</p> <p>9 Q. Okay.</p> <p>10 A. It could be .2 millimeters,</p> <p>11 roughly.</p> <p>12 Q. If you wanted to measure that on</p> <p>13 the slides that you have, can that be done?</p> <p>14 A. With a eyepiece micrometer, yes.</p> <p>15 Q. Anything else remarkable about</p> <p>16 Figure 2b other than showing the scar?</p> <p>17 A. Fiber bridging, and completely</p> <p>18 encapsulating the entire structure of mesh pores</p> <p>19 that fill the scar tissue, and normal tissue is</p> <p>20 outside. This is the mesh scar complex, or mesh</p> <p>21 scar plate.</p> <p>22 Q. As you look at this image, is this</p> <p>23 a complete slide?</p> <p>24 A. No, there is tissue beyond</p> <p>25 slightly. And this end, I think is here on the</p> | <p>1 the Edwards case, your best recollection?</p> <p>2 A. Yes.</p> <p>3 Q. And it's magnified ten times, and</p> <p>4 this is the one that is a magnification of the far</p> <p>5 right side of the image on page 23?</p> <p>6 A. Likely at different level.</p> <p>7 Q. What do you mean, a different</p> <p>8 slide?</p> <p>9 A. Different slide, yes.</p> <p>10 Q. Okay.</p> <p>11 A. So it's the same piece, but cut</p> <p>12 little deeper.</p> <p>13 Q. Now if you look on the top page of</p> <p>14 page 24, top image, on the right side there's a</p> <p>15 blue, that's again, displaced polypropylene?</p> <p>16 A. Yes, this is displaced</p> <p>17 polypropylene. And this as well (indicating).</p> <p>18 Q. Okay. And that's an artifact due</p> <p>19 to the microtoming process?</p> <p>20 A. It could've done that, yes.</p> <p>21 Q. And the description down below</p> <p>22 again is "fibrous bridging and scar encapsulation",</p> <p>23 does this image show anything in addition to what</p> <p>24 we've talked about in the prior slides?</p> <p>25 A. This is a terminal pore.</p> |
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| <p>1 next page, page 24.</p> <p>2 Q. Okay. We'll come to that in a</p> <p>3 second.</p> <p>4 A. That's my recollection.</p> <p>5 Q. The figure on 2a, page 22, is</p> <p>6 obviously a smaller part of a bigger slide, correct?</p> <p>7 A. That's correct.</p> <p>8 Q. And you believe that the image on</p> <p>9 page 23 is also a smaller part of a bigger slide?</p> <p>10 A. I think most of the mesh is here</p> <p>11 on the slide --</p> <p>12 Q. Um-hum.</p> <p>13 A. -- so there's not much mesh</p> <p>14 beyond.</p> <p>15 Q. That's why I'm asking the</p> <p>16 question.</p> <p>17 Does the image that's shown on page 23</p> <p>18 represent the outer boundaries of the mesh in that</p> <p>19 slide?</p> <p>20 A. I think so.</p> <p>21 Q. Okay.</p> <p>22 A. I think so, there's an edge of</p> <p>23 tissue here. Now, this exactly piece of this --</p> <p>24 Q. You've now turned the page, you're</p> <p>25 on page 24. So you believe this is probably from</p> | <p>1 Q. Sorry?</p> <p>2 A. This is a terminal pore of the</p> <p>3 mesh. So this is the edge of the mesh and the</p> <p>4 terminal pore contains normal non-scar tissue.</p> <p>5 Q. When you say "terminal pore"</p> <p>6 that's the outside pore?</p> <p>7 A. Yes, it is.</p> <p>8 Q. So what is the significance of the</p> <p>9 terminal pore having normal tissue?</p> <p>10 A. It just shows comparison. Pores</p> <p>11 which are not filled with scar tissue, and pores</p> <p>12 which are filled with scar tissue. So this</p> <p>13 specific pore contained normal scar tissue. So</p> <p>14 within that specific pore, there's no fibrous</p> <p>15 bridging.</p> <p>16 Q. Is it fair to say every place we</p> <p>17 see the blue, we see displaced polypropylene?</p> <p>18 A. Most of the time. It can be just</p> <p>19 a weird color of inflammation.</p> <p>20 Q. Okay. Anything else remarkable</p> <p>21 about the slide on page 24?</p> <p>22 A. No.</p> <p>23 Q. Okay. Let's go to page 25.</p> <p>24 A. Yes.</p> <p>25 Q. This is cited to an article. Do</p> |

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| <p>1 you know off the top of your head what article that 2 is? 3 A. On the safety of synthetic sling 4 surgery, I believe. 5 Q. Are you able to tell me what slide 6 that is, what plaintiff? Strike that. 7 Is that a medical-legal slide? 8 A. The picture comes from the same 9 case, as you can see it's exactly the same. 10 Q. Okay. Is B part of A? 11 A. No, I don't believe so. 12 Q. Let's talk about A. And what does 13 the "BF" mean? 14 A. "Bridging fibrosis". 15 Q. And the "AT"? 16 "Adipose tissue"? 17 A. Adipose tissue, yes. 18 Q. What is the significance of the 19 adipose tissue? 20 A. It's a normal non-scar tissue. 21 Q. So what is the significance of 22 including this slide in your report if it's the 23 same thing that you had in the prior two slides? 24 A. It's a little bit different. 25 Because, see, on the bottom, B, it shows scar</p> | <p>1 me the magnification of that image? 2 A. Close to times four maybe -- 3 because there's cropping and then the size was -- 4 now it's hard to -- it's much larger than it 5 appears in the publication. So I would say for 6 this specific, it would be close to times four 7 objective. 8 Q. If you go down here it says: 9 "Scar encapsulating mesh in 10 surrounding pre-existent normal 11 adipose tissue and muscle tissues, a 12 2.5 image of histological sections." 13 That means it's magnified 2.5 times. 14 A. It means that the objective you 15 would use to produce this appearance in the 16 microscope, this would be times 2.5. 17 Q. Okay. But the degree of 18 magnification is different from that? 19 A. On this page? 20 Q. Yes. 21 A. Yes. Because it's cropped and 22 resized and the publication is much smaller. 23 Q. I see. 24 A. So if you trace it, if more 25 correctly to trace it, to trace is the objective,</p> |
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| <p>1 tissue in a different stain. 2 Scar tissue may have some smooth 3 muscle, when the scar tissue is being remodeled by 4 myofibroblast. Myofibroblast can have smooth 5 muscle. But once it's mature scar tissue, there is 6 no contractile filament in the cells anymore, and 7 it doesn't stain with smooth muscles stain. 8 But, normal tissue of vaginal wall 9 contains smooth muscle. So here you can see that 10 the fibers bridging, can be separated from normal 11 tissue by using smooth muscle stain. 12 Q. And so the smooth muscle, or the 13 normal tissue is represented by the brown? 14 A. Yes. 15 Q. And this is another representation 16 of the fibrous bridging and scar encapsulations 17 depicted in blue? 18 A. Yes. 19 Q. Is that the only significance of 20 that stain? 21 A. Yes. 22 Q. Okay. 23 A. For this specific picture, yes, it 24 is. 25 Q. All right. Are you able to tell</p> | <p>1 you would use to see like this in the microscope. 2 Q. And you could use the optical 3 micrometer in order to measure to the extent 4 necessary? 5 A. Yes, I can. 6 Q. Anything else about this image? 7 A. No. 8 Q. Let's go to page 26, image 3a. 9 A. Yes. 10 Q. What's the purpose of this image? 11 A. This image shows the nerve in H&E 12 stain. 13 Q. What is the significance of 14 showing the nerve; just the fact that you can show 15 it? Is there any damage to it or any issues 16 associated with it? 17 A. It's normal nerve, it's present 18 within this mesh scar plate, it innervates the 19 tissue which is inside and outside of the mesh. It 20 can become trapped. 21 Q. Is it trapped in this image? 22 A. Well, it is in scar tissue. So 23 it's trapped in scar tissue. 24 Q. Is there any indication that this 25 nerve is damaged in this image?</p> |

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| <p>1 A. Not from this power, I don't see</p> <p>2 any -- "damage", you mean atrophic degenerated or</p> <p>3 damaged in terms of physical damage?</p> <p>4 Q. Any kind of damage.</p> <p>5 A. It is in scar tissue. For a nerve</p> <p>6 to be in scar tissue, is not a healthy environment.</p> <p>7 Q. But not all nerves in scar tissue</p> <p>8 produce symptoms, correct?</p> <p>9 A. Not all.</p> <p>10 Q. And you can't tell by looking at</p> <p>11 this image, whether the nerve in Figure Set 3a is</p> <p>12 producing any symptoms, correct?</p> <p>13 A. Again, it depends on timing. It</p> <p>14 may produce symptoms at one time and not produce at</p> <p>15 another time.</p> <p>16 If this specific nerve was producing</p> <p>17 pain sensation, it would be difficult to determine.</p> <p>18 Q. But you can't tell, looking at the</p> <p>19 nerve in Figure Set 3a, whether that nerve is</p> <p>20 producing symptoms for this patient, correct?</p> <p>21 A. I can tell you that this nerve is</p> <p>22 in a situation when it can produce symptom. This</p> <p>23 is the main thing I can say, it can because it is</p> <p>24 in an abnormal environment.</p> <p>25 Q. And the abnormal environment is</p> | <p>1 A. It's a mixed nerve.</p> <p>2 Q. What do you mean by "mixed nerve"?</p> <p>3 A. "Mixed" means they're both</p> <p>4 afferent and efferent, or motor and sensory signals</p> <p>5 going back and forth.</p> <p>6 Q. How can you tell it does both? Do</p> <p>7 all nerves do both?</p> <p>8 A. Peripheral nerves, yes.</p> <p>9 Q. All of them?</p> <p>10 A. Except for head.</p> <p>11 Q. Okay. So are all nerves in the</p> <p>12 body, peripheral nerves, capable of mediating pain?</p> <p>13 A. Except for cranial nerves.</p> <p>14 Q. Okay. And what's the basis for</p> <p>15 your understanding in that regard?</p> <p>16 A. It's a basic knowledge, it's in</p> <p>17 the textbooks.</p> <p>18 Q. Okay.</p> <p>19 A. There is some very small</p> <p>20 proportion of nerves, peripheral nerves, less than</p> <p>21 5 percent, which are only sensory. So some of the</p> <p>22 nerves will be only sensory. But there are almost</p> <p>23 no, only motor nerves outside of the cranial</p> <p>24 nerves.</p> <p>25 Q. Can you, by light microscopy,</p> |
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| <p>1 the presence in the scar tissue?</p> <p>2 A. Yes. In addition to be present</p> <p>3 inside the mesh.</p> <p>4 Q. Okay. Well, it's adjacent to the</p> <p>5 mesh, correct?</p> <p>6 A. I don't know. There might be</p> <p>7 fiber right there.</p> <p>8 Q. Okay.</p> <p>9 A. So it can be inside or outside, it</p> <p>10 doesn't matter. It's in scar tissue, it's abnormal</p> <p>11 environment, it can produce mesh. And we know that</p> <p>12 traumatic neuromas, which is the formation of a</p> <p>13 mesh in scar tissue, is a painful lesion. This is</p> <p>14 an established fact.</p> <p>15 Q. But there's no traumatic neuroma</p> <p>16 in this image, correct?</p> <p>17 A. A mesh is deformed, we can see</p> <p>18 it's getting there.</p> <p>19 Q. Can you see a traumatic neuroma in</p> <p>20 this image, 3a on page 26?</p> <p>21 A. The formation is not significant</p> <p>22 to call it a traumatic neuroma. So in this</p> <p>23 specific image, I would not use that term.</p> <p>24 Q. Now, can you tell whether the</p> <p>25 nerve on page 26 that you show is a motor nerve?</p> | <p>1 distinguish among the type of nerves which you see?</p> <p>2 A. What do you mean, what type of</p> <p>3 nerves?</p> <p>4 Q. Well, sensory and motor nerves?</p> <p>5 A. We just agreed that they're all</p> <p>6 mixed.</p> <p>7 Q. You said that, okay.</p> <p>8 Is there any way for you to distinguish</p> <p>9 by light microscopy which nerves are capable of</p> <p>10 mediating pain?</p> <p>11 A. They all are.</p> <p>12 Q. Okay. 5 percent you said, where</p> <p>13 are they?</p> <p>14 A. 5 percent is still sensory. So</p> <p>15 all of them can deliver pain. Some of them,</p> <p>16 5 percent, may not be able to do any motor</p> <p>17 function, but they will still be able to transmit</p> <p>18 pain. And it also depends on the size, because</p> <p>19 once you go into the very small branches, they</p> <p>20 become more specialized. If you go into the large</p> <p>21 trunk, then you get all of them mixed together.</p> <p>22 Q. When you talk about going into the</p> <p>23 nerve twigs, that's what you're talking about,</p> <p>24 right?</p> <p>25 A. Fibers, individual fibers, yes.</p> |

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| <p>1 Q. Then they become more specialized; 2 what do you mean by that? 3 A. So they may have more function for 4 sensory or motor function. 5 Q. So as the nerves break into twigs, 6 will there be some nerves that don't mediate pain, 7 or they still mediate pain? 8 A. Fibers. If you go into fibers 9 which is even smaller than twigs, which is 10 individual axon, those will have individual 11 function. 12 Q. And what are we looking at nerves 13 here; are we looking at twigs, fibers, or are we 14 looking at nerves? 15 A. It's a nerve. It's thicker than a 16 twig. 17 Q. Okay. And what is remarkable 18 about what you see in Figure 3a; anything more than 19 you've just described, the presence of a nerve 20 adjacent to mesh? 21 A. No, just everything else -- we 22 discussed everything significant. 23 Q. Now, the polypropylene in the 24 lower left-hand corner image, that's blue 25 polypropylene, correct?</p> | <p>1 A. Yes. For this specific image, 2 about 20 times -- 20 times objective magnification. 3 The magnification itself is higher, 4 because there's also an eyepiece, but eyepiece is 5 fixed. 6 Q. Look at the right side of that 7 image with the polypropylene. It's folded over, on 8 the right side; you'd agree with me there is no 9 bark? 10 A. Not visible bark. 11 Q. Okay. If we go to page 27, set 12 3b. 13 So 3a comes from the images from the 14 consolidated cases, correct? 15 A. That is correct. 16 Q. So we should have this slide, I 17 think. So paragraph 3b, so set 3b on page 27 says, 18 "additional TVT cases". 19 Are you able to tell me from which case 20 this slide comes? 21 A. I can only tell you that the top 22 panel is from a newer case, and the bottom is 23 likely from an older case. 24 Q. So they're two separate cases? 25 A. Yes.</p> |
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| <p>1 A. That's correct. 2 Q. And it's folded over as a part of 3 the sample preparation process or microtoming 4 process, correct? 5 A. That's correct. 6 Q. This is a 4 micron thick slide, 7 correct? 8 A. About 4 microns, plus or minus. 9 Q. I don't see bark on that 10 polypropylene. Do you see any bark on the 11 polypropylene? 12 A. There is a faint line here, I 13 don't know if it's there or not. 14 Q. When you say "there," you're not 15 pointing to the polypropylene. You're pointing to 16 the circular area to the left of the polypropylene 17 adjacent to the tissue, correct? 18 A. Yeah. Curving linear, yes. 19 Q. And you're suggesting that that 20 may be some bark? 21 A. Yes. 22 Q. And why do you say that? 23 A. Because it looks like it. 24 Q. Okay. And this is magnified at 20 25 times?</p> | <p>1 Q. Do you have any idea from looking 2 at this, how long the mesh was implanted in these 3 people? 4 A. No. Not at this magnification. 5 Q. And other than showing the 6 presence of nerves within the mesh scar plate like 7 you did on page 26, is there anything significant 8 about your findings on page 27? 9 A. The only difference is that in top 10 panel, you can clearly see that this nerve is 11 within the pore. 12 Q. Are you suggesting that this nerve 13 is inside of a single pour in the mesh? 14 A. Somewhere within the mesh. 15 Q. Okay. Not within the pore itself? 16 A. It can be within the pore. 17 Q. Do you know? 18 A. It also depends how you define the 19 pore. Pore is a hole in the mesh structure, yes, 20 it is within the space in the mesh structure. 21 Q. This is 20 times magnification, 22 how far is it from one yellow to the other yellow? 23 A. At 1.5 millimeter. Between 1 and 24 1.5 millimeter. 25 Q. Is there anything abnormal about</p> |

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| <p>1 the nerve that's depicted on page 27 in the top</p> <p>2 frame?</p> <p>3 A. It's in the scar and it's in the</p> <p>4 mesh, that is abnormal.</p> <p>5 Q. Other than being in the scar</p> <p>6 plate, is there anything you can tell by light</p> <p>7 microscopy about abnormality in that nerve?</p> <p>8 A. Otherwise, the nerve looks</p> <p>9 healthy, it would conduct pretty healthy pain</p> <p>10 signals.</p> <p>11 Q. Okay. Same thing for the lower</p> <p>12 frame. Other than the presence of the nerve within</p> <p>13 the scar tissue, is there anything that you can</p> <p>14 tell from light microscopy about the general health</p> <p>15 of the nerve?</p> <p>16 A. Same thing, it's not degenerated,</p> <p>17 therefore, it can conduct pain signal.</p> <p>18 Q. As you look at the image on the</p> <p>19 lower left on 3b, the white in that image, again,</p> <p>20 is where polypropylene was?</p> <p>21 A. Yes.</p> <p>22 Q. And as you come down around from</p> <p>23 about 6 o'clock to about 9 o'clock, there's no bark</p> <p>24 there, is there?</p> <p>25 A. No. I don't think so.</p> | <p>1 A. There are two nerves, one is here,</p> <p>2 one is there (indicating).</p> <p>3 Q. And you indicate that with your</p> <p>4 two arrows --</p> <p>5 A. This one is gone.</p> <p>6 Q. Okay.</p> <p>7 A. So it is a location -- it's not</p> <p>8 the nerve itself, it's the location is abnormal.</p> <p>9 Q. Is there anything that you can</p> <p>10 tell me by looking at this image by light</p> <p>11 microscopy that these nerves were producing</p> <p>12 symptoms in the patient?</p> <p>13 A. The question is, if they can.</p> <p>14 Q. Can you tell me by looking at this</p> <p>15 image in set 3c, that these nerves are causing</p> <p>16 symptoms in the patient?</p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: Again, as a pathologist,</p> <p>19 I can only estimate the probability. If it can, if</p> <p>20 it's in abnormal location, if it's causing a lot --</p> <p>21 first of all, it's out of the body now, so it</p> <p>22 cannot cause anything. But when it was in the</p> <p>23 patient, it could.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Could?</p> |
| Page 139 | Page 141 |
| <p>1 Q. Let's go to page 28. Page 28 is</p> <p>2 additional TVT cases.</p> <p>3 Is this one mesh or two? One patient</p> <p>4 or two, I guess I should say.</p> <p>5 A. This is hard to say, both are come</p> <p>6 from earlier cases. I probably have thousands of</p> <p>7 images by now, so it will be hard.</p> <p>8 Q. But you can't tell me from which</p> <p>9 patient they come, or which case they're from?</p> <p>10 A. I may or may not be able. It</p> <p>11 would be checking if it's in a specific folder or</p> <p>12 just in pooled images.</p> <p>13 Q. And your description again, below</p> <p>14 is, "Innervation within the mesh scar plate, H&E,</p> <p>15 20 times magnification."</p> <p>16 Other than showing the presence of</p> <p>17 these nerves in the mesh scar plate, is there</p> <p>18 anything that indicates to you by light microscopy</p> <p>19 that these nerves are unhealthy?</p> <p>20 A. Well, it's the location. You see,</p> <p>21 it's slightly curved, it's inside the pore.</p> <p>22 Q. Which one are you talking about</p> <p>23 now, please?</p> <p>24 A. The upper panel.</p> <p>25 Q. Okay, thank you.</p> | <p>1 A. Could produce symptoms all the</p> <p>2 time, or one specific time, or only once in a</p> <p>3 specific moment, it's hard to say.</p> <p>4 Q. And it could be a nerve positioned</p> <p>5 as it is, that never produced any symptoms, true?</p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: Some of them probably not</p> <p>8 producing anything.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Okay. And the same thing about</p> <p>11 the image below on Figure Set 3c on page 28, other</p> <p>12 than presence of the nerves in the mesh scar plate,</p> <p>13 anything remarkable about this image?</p> <p>14 A. No. Nothing beyond what we've</p> <p>15 discussed.</p> <p>16 Q. Let's go to page 29.</p> <p>17 A. Yes.</p> <p>18 Q. What are we showing on page 29?</p> <p>19 A. The same features of innervation</p> <p>20 of the mesh scar plate. But now in S100 stain.</p> <p>21 Q. Now, is there anything other than</p> <p>22 presence of these nerves in the mesh scar plate</p> <p>23 that indicates to you that these nerves were</p> <p>24 causing pain in the patient?</p> <p>25 A. They are in abnormal location.</p> |

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| <p>1 Q. And we've already agreed that</p> <p>2 nerves, even in an abnormal location, may not be</p> <p>3 producing pain, correct?</p> <p>4 A. Yes, but more likely they will</p> <p>5 produce pain.</p> <p>6 Q. Are you saying that every nerve</p> <p>7 within the mesh scar plate more likely than not is</p> <p>8 going to cause pain?</p> <p>9 A. Through one mechanism or the</p> <p>10 other, there will be zero mechanism at one point</p> <p>11 that can produce pain, it may not be chronic pain</p> <p>12 continuous, but I mean, in a specific movement you</p> <p>13 have start forming the mesh, so it can cause pain.</p> <p>14 Q. Let's talk about this for a</p> <p>15 minute. Doctor, if you look at page 29, and 28,</p> <p>16 and 27 and 26 --</p> <p>17 A. Yes?</p> <p>18 Q. -- it's fair to understand that</p> <p>19 for every mesh implantation, there are going to be</p> <p>20 nerves that are going to be in scar tissue.</p> <p>21 A. Are you talking for all meshes?</p> <p>22 Regardless of location, or just --</p> <p>23 Q. I'm talking about slings. Stress</p> <p>24 urinary incontinence slings, TVT, Prolene.</p> <p>25 A. So for slings, there will be</p> | <p>1 A. Well, first of all, let's start</p> <p>2 with 5 percent.</p> <p>3 That number would have to be specific</p> <p>4 for our study. There is a range of reported pain</p> <p>5 anywhere from 5 to 40 plus percent. It depend on</p> <p>6 methodology, if the patients were followed in time</p> <p>7 correctly, if there was correctly of follow up</p> <p>8 time. So the 5 percent is a questionable number.</p> <p>9 Q. Can I interrupt you there, if you</p> <p>10 don't mind. Let's take your upper bound of</p> <p>11 40 percent?</p> <p>12 A. Yes.</p> <p>13 Q. So you have, by your own</p> <p>14 statement, even in the worse case scenario, you</p> <p>15 have 60 percent of the sling patients who don't</p> <p>16 experience pain, correct?</p> <p>17 A. Who do not complain to the point</p> <p>18 when it's recorded.</p> <p>19 There are multiple reasons why it may</p> <p>20 not be recorded, they may still experience some</p> <p>21 pain. Maybe it's not serious enough to be</p> <p>22 recorded, maybe it's not serious enough -- there</p> <p>23 will be some patients which have no pain at all.</p> <p>24 There will be some patients which have so little</p> <p>25 pain, only in a specific moment, that it's not</p> |
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| <p>1 innervation, at least those samples I examined,</p> <p>2 there will be innervation in all of them.</p> <p>3 Q. Okay. And complaints of pain for</p> <p>4 slings, TVT slings, you'll agree is less than 5</p> <p>5 percent?</p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: For the specimens I</p> <p>8 received?</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. I'm talking about the studies on</p> <p>11 the topic?</p> <p>12 MR. ORENT: Objection. Outside the</p> <p>13 scope.</p> <p>14 THE WITNESS: Now we're talking about</p> <p>15 what I received and what is still in the patients.</p> <p>16 Because studies were clinically done based on</p> <p>17 clinical -- clinical symptoms for the samples or</p> <p>18 slings which are still in the body.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Very simple question.</p> <p>21 How do you explain findings in the</p> <p>22 clinical studies that pain is a complaint of</p> <p>23 patients in less than 5 percent of the time, when</p> <p>24 you say in every mesh that you see, that there are</p> <p>25 nerves within the scar plate?</p> | <p>1 worth reporting. Some of them don't report it and</p> <p>2 so forth.</p> <p>3 And then there will be patients that</p> <p>4 there is so severe pain, the mesh needs to come</p> <p>5 out. There will be a range of sensations and</p> <p>6 personal perception.</p> <p>7 So, from my perspective, when I examine</p> <p>8 specimens, I report what is abnormal. To what</p> <p>9 degree it's causing clinical symptoms, it depends</p> <p>10 on many factors. If you want to -- you cannot look</p> <p>11 at the human body as a machine. I mean, there is</p> <p>12 part missing, it's not going to work. Or if there</p> <p>13 is wire loose, I mean, it may cause some problems.</p> <p>14 So, there will be a range of -- or</p> <p>15 degree of pain sensation and a range of personal</p> <p>16 attitude so this will effect the recording of</p> <p>17 clinical symptoms.</p> <p>18 On the histology side, again, there</p> <p>19 will be a range of how many nerves are involved,</p> <p>20 one or two, or a really high density. To what</p> <p>21 degree they are involved, some of them will have</p> <p>22 such a strong deformation, that there is</p> <p>23 100 percent probability that it will cause pain.</p> <p>24 Q. Let me ask this question --</p> <p>25 A. So that's the complexity of the</p> |

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| <p>1 situation. I mean you cannot separate it sharply, 2 okay, 5 percent for this, 5 percent for that. It 3 can cause a pain. This is abnormal location, this 4 is abnormal situation, this is a pathological 5 finding. 6 Q. Let's talk about this for a 7 minute. So the pages we've just been through, 8 we've talked about, on pages 26, 27, 28 and 29, and 9 it goes on to 30 and 31, and on to 33. But just 10 for those for now. 11 Is it fair to understand that in every 12 mesh that you've analyzed - regardless of 13 manufacturer - in the pelvic floor, for treatment 14 of stress urinary incontinence, you find nerves in 15 scar tissue? 16 A. Yes. 17 Q. Okay. 18 A. The degree of innervation will be 19 different, there will be a degree of also nerve 20 deformation within the mesh, but strictly saying 21 there will be innervation of the scar plate in 22 almost all patients. 23 Q. Have you made any attempt to 24 differentiate across manufacturers, the extent to 25 which the innervation of the scar plate varies?</p> | <p>1 -- REPORTER'S NOTE: Question read as 2 recorded above. 3 THE WITNESS: Oh, as I said, I can only 4 testify or make opinions of what came out of the 5 specimen. And I told you earlier, that there is -- 6 I have been dealing with those specimens which 7 caused complications already. 8 BY MR. THOMAS: 9 Q. For every mesh sample that you've 10 looked at for mesh use for the treatment of stress 11 urinary incontinence, have you found mesh 12 innervation in the scar tissue? 13 A. Almost all, yes. 14 Q. Any you haven't? 15 A. If it was a small sample, maybe 16 one or two, I couldn't find nerves. 17 Q. Is that because -- do you have an 18 opinion, is that because the sample was too small, 19 because it didn't exist, or do you have an opinion? 20 A. I cannot say beyond that, I just 21 didn't find it. It could be sampling issue, it 22 could be not. Again, I cannot state what I don't 23 know. 24 Q. And how many have you seen? 25 A. Individual cases.</p> |
| Page 147 | Page 149 |
| <p>1 A. No. 2 Q. Have you made any attempt to 3 differentiate across types of mesh products, the 4 extent to which nerve innervation varies? 5 A. I may in the future, I haven't 6 done it yet. But I may in the future. 7 Q. Okay. So is it fair for me to 8 understand, and the record to reflect, that for 9 every mesh implanted for the treatment of stress 10 urinary incontinence, it's your opinion that there 11 will be nerve innervation within scar plate, that 12 you think is capable of causing pain? 13 MR. ORENT: Objection. I think his 14 testimony is every mesh that he's looked at. 15 Manufactured, that he's looked at. 16 I don't think Dr. Iakovlev has any 17 opinions about mesh he's never looked at, brands 18 he's never looked. 19 THE WITNESS: Yeah, that's correct. 20 BY MR. THOMAS: 21 Q. Okay. Let me ask you this question -- 22 A. Let's repeat the question, then I 23 can answer it in more... 24 MR. THOMAS: Would you read it back, 25 please?</p> | <p>1 Q. How many have you seen? 2 A. Less than five. 3 Q. How many total cases have you 4 seen? 5 A. Oh, from slings? 6 Q. Yes. 7 A. About 100. 8 Q. About 100. And less than five you 9 have not seen nerve innervation within scar tissue? 10 A. Yes. 11 Q. And you don't know whether that's 12 because it is a sampling error or because there 13 wasn't any nerves in the scar plate? 14 A. That's correct. 15 Q. Is it fair to say, based on your 16 experience as a pathologist, that you would expect 17 that when mesh is placed for the treatment of 18 stress urinary incontinence, that nerves would be 19 encapsulated by the scar tissue in the healing 20 process? 21 A. They can. If they become trapped 22 in the scar tissue, each single implanted mesh, we 23 would have to do autopsy series. I cannot go 24 beyond what I see in explanted meshes, and all 25 explanted meshes came out for complications. And</p> |

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| <p style="text-align: right;">Page 150</p> <p>1 almost all of them, or a large proportion had pain 2 as a symptom. 3 Q. Again, the cases you've received 4 have been complications? 5 A. Yes. 6 Q. And of course you know that people 7 have mesh removed for reasons other than pain, 8 don't you? 9 A. In hernia surgery, yes. 10 Q. Do you know whether or not 11 patients have mesh removed for reasons other than 12 pain? 13 MR. ORENT: Objection. 14 THE WITNESS: There might be an 15 overwhelming other complaint, like erosion or 16 infection, but in almost -- I don't want to stick a 17 number, but most of these patients complain of some 18 degree of pain. 19 BY MR. THOMAS: 20 Q. Have you have investigated, as a 21 part of your work in this case, the reasons why 22 patients have mesh removed? 23 A. There's always a reason. 24 Q. I understand that. Do you know 25 what they are, and percentage wise, how they</p> | <p style="text-align: right;">Page 152</p> <p>1 THE WITNESS: No, it's combined. It 2 can be combined, this pain. 3 BY MR. THOMAS: 4 Q. Okay. 5 A. To cause void and dysfunction, 6 even to compress urethra to a degree that the 7 outflow is obstructed. 8 Q. Are you aware of any studies which 9 have analyzed meshes removed because of pain, 10 compared to meshes removed for other reasons in 11 comparing the histology of those meshes? 12 A. We're doing some work in hernia 13 specimens. 14 Q. But in terms of published 15 peer-reviewed studies today, are you aware of any 16 studies out there, which compare the histology of 17 meshes removed for pain, and meshes removed for 18 non-pain reasons? 19 A. That's a very good question. Why, 20 after 50 years and a large proportion of specimens 21 removed for pain, there is no histology study. Why 22 has this not been done? 23 Q. So did you do a literature search 24 of that? 25 A. Of course I did.</p> |
| <p style="text-align: right;">Page 151</p> <p>1 breakout across a patient population? 2 A. You mean the driving reasons for 3 implantation? 4 Q. Yes. 5 A. It's in the paper. At least in 6 those 164 samples. 7 Q. And that's the paper you did with 8 Dr. Blaivas? 9 A. No. The degradation paper. 10 Q. Okay. 11 A. But there's always a driving 12 reason for explantation. There may be driving 13 reason for explantation is erosion, but then pain 14 is attributed to erosion. So it's not indicated as 15 a main reason of explantation. 16 Q. You can have voiding dysfunction? 17 A. Okay. In a voiding dysfunction, 18 but again, voiding dysfunction usually what 19 happens, you have a strong compression against 20 urethra, and this produces pain due to compression. 21 So there will be a mixture of mechanisms for pain. 22 Q. Are you suggesting that voiding 23 dysfunction is subsumed within the pain that's 24 reported in these studies? 25 MR. ORENT: Objection.</p> | <p style="text-align: right;">Page 153</p> <p>1 Q. And you didn't find any studies 2 that compared the histology of mesh removed from 3 patients who complained of pain, compared to the 4 histology of patients who had mesh removed for 5 non-pain reasons? 6 A. There were descriptions in hernia 7 publications. I mean in meshes removed for hernia 8 repair. 9 Q. Which studies, do you remember? 10 A. 2005, Klosterhalfen. He put the 11 picture of deformed nerve, and he states that in 12 his experience, over 60 percent of the meshes 13 removed for pain have some degree of nerve 14 involvement. 15 Q. Do you view Dr. Klosterhalfen as 16 authoritative in this area? 17 A. Yes. He's an authority, he's one 18 of the oldest researchers. 19 Q. Do you know whether Dr. 20 Klosterhalfen has ever investigated the precise 21 question about whether the histology of mesh 22 removed for indications of pain is different from 23 the histology of mesh for -- from patients removed 24 for non-pain reasons? 25 A. That's what he stated. Over</p> |

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| <p style="text-align: right;">Page 154</p> <p>1 60 percent of the specimens removed for pain showed 2 nerve involvement. 3 MR. ORENT: Before we go on to the next 4 question, you had cut Dr. Iakovlev off from 5 answering. He started to say "but there are other 6 authors", if you want to just continue. 7 THE WITNESS: Yes. There are other 8 descriptors of meshes removed for pain, and they 9 would find nerve involvement with traumatic 10 neuroma. Those are, I think individual cases, not 11 the series. 12 Again, same histology. They were 13 trying to figure out what was wrong, what was 14 causing pain, and they found nerve involvement. 15 And that was done before I started researching my 16 nerves. 17 BY MR. THOMAS: 18 Q. Would you expect more or less 19 inflammation to be seen in histology of meshes 20 removed for pain than meshes removed for non-pain 21 reasons? 22 A. To a degree. My research in 23 hernia showed that foreign body inflammation is a 24 component of pain mechanism. So those meshes which 25 were removed for pain only, they continue to have</p> | <p style="text-align: right;">Page 156</p> <p>1 there's a pool, if we collect enough, we can see 2 the difference. For each individual patient, how 3 much of this feature, or that feature is playing a 4 role in each individual symptom, will be very 5 different from patient to patient. 6 So overall, the higher degree of 7 foreign body reaction is associated with higher 8 rates for chronic pain. 9 Q. And that's based on your research 10 or other published research? 11 A. Foreign body has been worked up 12 quite a bit in published histological studies. How 13 much of that was specifically determined, comparing 14 two groups or three groups, it's difficult to say, 15 I don't remember right now. 16 So it is a combination of what was 17 published before, and what I find in my samples, so 18 that's -- that would be a basis for my opinion. 19 Q. Is it your opinion that results in 20 the hernia literature on the issue of association 21 between inflammation and pain, are transferrable to 22 the pelvic floor? 23 A. Some are, yes. Not everything, 24 but some are. 25 Q. Okay. And why would it not be?</p> |
| <p style="text-align: right;">Page 155</p> <p>1 relatively steady, pronounced foreign body reaction 2 many years after implantation. 3 And those which were removed for 4 recurrence, they show a trend down. So at the 5 beginning, there is inflammation, then it goes 6 down. 7 So by the time of explantation, if it 8 happens eight years or ten years after 9 explantation, foreign bodies subsided; which is 10 different from those which were removed for pain. 11 Q. So are you able, from your 12 research, in your work, to form an opinion as to 13 whether mesh removed for purposes of pain, the 14 histology will show higher rates of inflammation 15 than the histology for meshes removed for non-pain 16 reasons? 17 A. So before we go into the 18 individual findings, you're trying to split it into 19 what is causing the pain, nerve entrapment and 20 inflammation or something else. 21 This is a complex process. There are 22 multiple factors which are playing, together with 23 patient perception of pain and reporting of pain. 24 So with this type of complexity, we 25 cannot separate one individual feature. Overall,</p> | <p style="text-align: right;">Page 157</p> <p>1 A. There are different anatomical 2 locations, different physical factors acting on the 3 scar plate. It also crosses many anatomical planes 4 in the pelvis. While in the abdominal wall, and 5 it's parallel to anatomical planes. 6 Q. I'm trying to get through this for 7 a second. If you'll look at pages 30, 31, 32 and 8 33. Are the images on those pages additional 9 depictions of nerves within the mesh scar plate? 10 A. That's correct. 11 Q. Is there anything else significant 12 about those images other than they show innervation 13 within the mesh scar plate? 14 A. No. 15 Q. On page 33, Figure Set 3h, in the 16 upper right-hand corner, you've called out what 17 you've described as a "neurovascular bundle"; what 18 is that? 19 A. Most of the larger nerves in the 20 medium size arteries, become together. One artery, 21 two veins, and one nerve, that's how it works. And 22 the nerve just starts bleeding, so the nerve goes 23 its way and artery goes its own way. 24 So in this specific case, an artery and 25 a nerve are still together.</p> |

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| <p style="text-align: right;">Page 158</p> <p>1 Q. Okay. The brown is the nerve, 2 correct? 3 A. Yes. I mean, there are some other 4 brown, probably picking up some other stuff, but 5 this is -- 6 Q. Where is the artery? 7 A. In the blue. You can see 8 streaming, it's not a really high resolution. 9 Q. What is the significance of the 10 neurovascular bundle as depicted in that image? 11 A. Well, see, it is in the tight 12 spot. So this is really as compartmentalized as it 13 gets, and slightly deformed. 14 So if you move this mesh around, the 15 fibers will start compressing on the neurovascular 16 bundle. It may cause obliteration of the artery, 17 or can impinge the nerve. 18 Q. Is there any impingement shown in 19 this image? 20 A. Well, it's deformed. 21 Q. Is there any impingement shown? 22 A. It does, because it's deformed, 23 it's curved. 24 Q. And you're referring now to the 25 lower right-hand image?</p> | <p style="text-align: right;">Page 160</p> <p>1 Q. Do you know? 2 MR. ORENT: Objection. 3 THE WITNESS: With 100 percent 4 certainty, no. 5 BY MR. THOMAS: 6 Q. Okay. And you talked about an 7 obliteration of the artery. Does the image on 8 page 33 in the upper right show an obliteration of 9 the artery? 10 A. No, not this image. 11 Q. Other than the nerve impingement 12 that you've described, and the potential for 13 obliteration of the artery, is there anything 14 unusual about the depiction of the nerves in those 15 images? 16 A. No. 17 Q. And I need you to go back, because 18 I didn't ask you that question about the prior two 19 pages, 30 through 32. 20 Other than the depiction of the nerves 21 within the scar plate, is there anything about the 22 nerves that are seen there that cause you any 23 concern about the potential of those nerves to 24 cause injury? 25 MR. ORENT: Objection.</p> |
| <p style="text-align: right;">Page 159</p> <p>1 A. That's correct. 2 Q. Is there anything you can tell by 3 looking at that image, whether that curved nerve 4 was causing pain in this patient? 5 A. I can say the probability of this 6 causing pain is much higher than a nerve which is 7 not deformed. Like something like this on page 31. 8 Q. You can't rule out by looking at 9 the image on page 33, where you show the curved 10 nerve, you can't rule out that that nerve is not 11 causing pain, correct? 12 A. I think we're going back to the 13 same issue. You're taking human body as a machine, 14 it's not. Medicine doesn't happen like that. So 15 there are many, many, many factors which cause. 16 If the same image we put in MRI image, 17 and this deformation would be on the root coming 18 from the back, the radiologist would report that 19 there's impingement of a root. And that's how back 20 pain occurs that's radiating to the leg, and so 21 forth. So this is a much smaller scale, the same 22 mechanism. 23 Q. Do you know whether this patient 24 was complaining of pain? 25 A. Most likely she was.</p> | <p style="text-align: right;">Page 161</p> <p>1 THE WITNESS: So going back to 2 mechanisms of pain. So there are two mechanisms, 3 or two major groups of mechanisms to cause pain. 4 First, you affect the nerve itself. So you impinge 5 it, squeeze it, becomes deformed and that can be 6 felt as pain, the nerve itself, the nerve trunk. 7 The second group of mechanisms is when 8 you affect the receptors. And the receptors can be 9 affected, it can be again a mechanical trauma, 10 cutting, compressing, burning, chemical trauma, 11 ischemia, then the receptors are signalling pain 12 through the nerve. So for smaller branches, the 13 significance is that the receptors now can pick up 14 the signal of nerves -- of pain, and then it will 15 be delivered through these branches, so it just 16 shows that this tissue can sense pain. 17 BY MR. THOMAS: 18 Q. Okay. This tissue is capable of 19 sensing pain? 20 A. Yes. 21 Q. Not that it is in fact sensing 22 pain in the body at the time? 23 A. If you have other mechanisms to 24 deliver pain, it will be -- it will be causing 25 pain.</p> |

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| <p>1 Q. Correct.</p> <p>2 A. Now, if you go to page 33, this</p> <p>3 will be an example where it would be directly</p> <p>4 effecting the nerve trunk. Impingement of the</p> <p>5 nerve.</p> <p>6 Q. Now, are you able, in these</p> <p>7 images, 30 to 33, to show me any nerve receptors?</p> <p>8 A. You mean receptors, nerve endings.</p> <p>9 When it goes really small, you can see really</p> <p>10 fiber, and it is -- most of the ends will have no</p> <p>11 staining, because they just disappear. But I mean,</p> <p>12 you'd have to go in higher magnification.</p> <p>13 Q. So with the magnification you have</p> <p>14 here, you're not able to identify any nerve</p> <p>15 receptors; is that fair?</p> <p>16 A. No, not in these pictures. It's</p> <p>17 too small magnification.</p> <p>18 Q. I have to ask the question again</p> <p>19 because you answered "no" to a negative question.</p> <p>20 It's fair to understand that based on</p> <p>21 the magnification that you have in these images on</p> <p>22 pages 30 to 33, you can't identify any nerve</p> <p>23 receptors, correct?</p> <p>24 A. I cannot see nerve receptors at</p> <p>25 this degree of magnification.</p> | <p>1 and the lower one was four times; is that correct?</p> <p>2 A. It's a typo, it should be 40.</p> <p>3 Q. 40?</p> <p>4 A. 40. Somewhere between 40 X and 50 X.</p> <p>5 Again, the cropping factor there, the magnification</p> <p>6 there is not exactly...</p> <p>7 Q. And these are, again, additional</p> <p>8 TVT cases, and you have not supplied us the slides</p> <p>9 for these cases, correct?</p> <p>10 MR. ORENT: Objection.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. In this case?</p> <p>13 A. That's correct. These are</p> <p>14 previous TVT cases.</p> <p>15 Q. On page 35 --</p> <p>16 A. Yes.</p> <p>17 Q. -- you suggest degeneration of</p> <p>18 affected nerves; tell me what you mean by that?</p> <p>19 A. So you see the inner portion of</p> <p>20 the nerve lost myelination. So there is</p> <p>21 degeneration of myelin sheath in the nerves. It</p> <p>22 means that these nerves cannot deliver, or most</p> <p>23 likely not deliver irregular signals.</p> <p>24 So earlier you were asking about the</p> <p>25 abnormality, this is the abnormality that we're</p> |
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| <p>1 Q. Thank you.</p> <p>2 If you go to page 34, what is the</p> <p>3 significance of this image?</p> <p>4 A. This shows another severely</p> <p>5 deformed nerve. So this would be a mechanism for</p> <p>6 pain through impingement.</p> <p>7 Q. And the severely deformed nerve as</p> <p>8 you described it, is the brown portion, stained</p> <p>9 brown?</p> <p>10 A. The dark brown portion or dark</p> <p>11 brown structure.</p> <p>12 Q. And in the lower left-hand corner,</p> <p>13 the white area is where the polypropylene is or</p> <p>14 was, correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And what's the significance of the</p> <p>17 dark blue and the border of that area? Is that the</p> <p>18 staining mechanism, or does that tell you anything?</p> <p>19 A. Can you point it? So significance</p> <p>20 of what?</p> <p>21 Q. The darker blue.</p> <p>22 A. This dark blue?</p> <p>23 Q. Yes.</p> <p>24 A. That's inflammation.</p> <p>25 Q. Okay. And the upper is 2.5 power,</p> | <p>1 talking about, this is the nerve degeneration. In</p> <p>2 this case, if this part is sensory, inside, it</p> <p>3 means that the area is numb.</p> <p>4 This part of the nerve cannot sense</p> <p>5 pain or innervation of that part of the body, which</p> <p>6 goes through this nerve, may not experience any</p> <p>7 pain; it's numb.</p> <p>8 Q. And that's the portion you're</p> <p>9 referring to in the lower right-hand image with the</p> <p>10 arrow, correct?</p> <p>11 A. That's correct. So the</p> <p>12 abnormality of the neural section indicates the</p> <p>13 other process, of loss of sensation, loss of pain</p> <p>14 sensation.</p> <p>15 Q. Do you know what a Renault body is?</p> <p>16 A. Say that again.</p> <p>17 Q. Do you know what a Renault body is?</p> <p>18 R-E-N-A-U-T.</p> <p>19 A. I think I've seen this term, but I</p> <p>20 don't remember it.</p> <p>21 Q. Okay. Does the S100 stain all</p> <p>22 components of the nerve?</p> <p>23 A. It only stains schwann cells.</p> <p>24 Q. When you reached the opinion on</p> <p>25 page 35 that that shows a degeneration of the</p> |

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| <p>1 nerve, did you rule out the presence of nerve 2 structures other than schwann cells that might be 3 present? 4 A. There might be axons still there, 5 but that's not the point. The point is the nerve 6 is degenerating. 7 Q. And what's the clinical impact of 8 the degenerated nerve? 9 A. I just told you. There are 10 fibers, which are in the area, mainly not function. 11 It means that if they are sensory fibers, they may 12 not deliver signals. So that area which is 13 innervated through those fibers, will be numb. You 14 will not feel anything in that area. 15 Q. So it will not cause pain? 16 A. In the reverse, it will not feel 17 anything. 18 Q. But if it doesn't feel anything, 19 does that mean that it does not cause pain? 20 A. Including pain. It will not feel 21 touch, it will not feel temperature, it will not 22 feel pain. 23 Q. Okay. Anything else remarkable 24 about it then? 25 A. No.</p> | <p>1 on page 36 -- strike that. 2 This is one image, the second one 3 you've labeled, so it's just one image? 4 A. That is correct. 5 Q. Is there anything about the image 6 on page 36, that you can tell by light microscopy, 7 that there's anything abnormal about the ganglia 8 that's depicted there? 9 A. To begin with, as we saw the 10 nerves, the location was abnormal. So it's in the 11 scar tissue and it's inside the mesh. 12 Q. Is that the only thing about this 13 image and the ganglia that causes you concern? 14 A. No. 15 Q. What else? 16 A. I mean, that's about it. I don't 17 have any other concerns. 18 Q. Thank you. Page 37 you have: 19 "Innervation of mucosa overlying the mesh, H&E and 20 S100 of the same tissue area, four times. 21 Additional TVT cases." 22 Again, these are cases outside of the 23 consolidated group, correct? 24 A. That is correct. 25 Q. And are all these images just four</p> |
| Page 167 | Page 169 |
| <p>1 Q. If you go to page 36, Figure Set 4. 2 A. Yes. 3 Q. You have, "A neural ganglia in 4 additional TVT cases." 5 Again, these are cases that you 6 previously worked up? 7 A. That is correct. 8 Q. What is a neural ganglia? 9 A. Neural ganglion is like a switch 10 box, or connection box for the autonomous 11 neuro system. The neuro system which is 12 innervating in the organs rather than skin and 13 mucosa. 14 Q. What is the significance of the 15 presence of this image of the neural ganglion? 16 A. It tells you that some of the 17 nerves, which we see in the specimens are 18 autonomous. So some of them go into the bladder. 19 That's one -- well, one important aspect of this. 20 The second important aspect is that the 21 ganglia themselves can be affected by the image. 22 So in first case, the nerves can be 23 affected, which are further away from the ganglia. 24 And second case scenario, the ganglia themselves. 25 Q. Is there anything about this image</p> | <p>1 times? 2 A. The degree of magnification on the 3 top image is slightly lower, and magnification on 4 the lower is slightly higher. Again, this is 5 not -- it's hard to say exactly what's the degree 6 of magnification. Because they've been taken 7 through a camera and sort of objective, and then 8 cropped, and then resized to be reprinted so... 9 Q. What is the significance of the 10 image on the top where you showed mucosa, distorted 11 mucosa, and a measurement of 1 millimeter? 12 A. Significance is that the mesh is 13 right under the mucosa. So, if you touch the 14 mucosa, even if it's light pressure, it immediately 15 gets compressed into the mesh. It can be exposed, 16 I mean, the mucosa can breakdown. 17 Q. This is from the Edwards case, 18 isn't it? 19 A. It could be, I don't know. It's 20 old picture, it could be from the Edwards case. 21 Q. And this does not show an 22 exposure, correct? 23 A. It's not exposed, yes. 24 Q. It's not an erosion either yet? 25 A. In this specific image, it's not</p> |

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| <p style="text-align: right;">Page 170</p> <p>1 exposed.</p> <p>2 Q. Okay. And what's the significance</p> <p>3 of the distorted mucosa?</p> <p>4 A. Probably, it was getting close to</p> <p>5 the exposure site. I don't remember specifics.</p> <p>6 Q. Okay. But is it simply the fact</p> <p>7 of the location of this mesh related to the mucosa</p> <p>8 that you're pointing out here?</p> <p>9 A. That is correct.</p> <p>10 Q. Is that a surgical placement issue?</p> <p>11 A. Not exactly. It can migrate, it</p> <p>12 can move centimeters within the body.</p> <p>13 Q. Or a surgeon can place it there,</p> <p>14 correct?</p> <p>15 A. Both.</p> <p>16 Q. Yes. And you're not able to tell</p> <p>17 from this image, whether the surgeon placed it</p> <p>18 there or it moved there from somewhere else,</p> <p>19 correct?</p> <p>20 A. No. I know that all of them are</p> <p>21 covered by mucosa after surgery. That's what</p> <p>22 surgeons are trying to do.</p> <p>23 Q. So again, I asked a bad question.</p> <p>24 You can't tell from looking at the</p> <p>25 image, whether the surgeon placed it there, or</p> | <p style="text-align: right;">Page 172</p> <p>1 anything else remarkable about that image?</p> <p>2 A. No.</p> <p>3 Q. If we go to page 39, what is</p> <p>4 vascular dilatation?</p> <p>5 A. When the vessels are being</p> <p>6 distended, so the outflow from the vessels is</p> <p>7 obstructed for varying reasons. So there is more</p> <p>8 fluid coming in, than fluid coming out.</p> <p>9 Q. And what does mesh have to do with</p> <p>10 vascular dilatation?</p> <p>11 A. It caused it.</p> <p>12 Q. How do you know that?</p> <p>13 A. Because normally vessels are not</p> <p>14 distended like this, there is a reason why the</p> <p>15 outflow is obstructed.</p> <p>16 Q. Are there any other causes for</p> <p>17 vascular dilatation?</p> <p>18 A. In normal tissue?</p> <p>19 Q. Yes.</p> <p>20 A. There are some other, like typical</p> <p>21 example is hemorrhoids.</p> <p>22 Q. I'm sorry?</p> <p>23 A. Hemorrhoids.</p> <p>24 Q. Hemorrhoids?</p> <p>25 A. Hemorrhoids.</p> |
| <p style="text-align: right;">Page 171</p> <p>1 whether it migrated there, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Thank you. And what's the</p> <p>4 significance of the two images below that on</p> <p>5 Figure Set 5?</p> <p>6 A. It's the same image, the right</p> <p>7 copy is labeled, the left one is not labeled. It</p> <p>8 shows that the tissue in between mucosa and the</p> <p>9 mesh is innervated.</p> <p>10 Q. I see.</p> <p>11 A. So if you compress mucosa, you are</p> <p>12 hitting the receptors, hence small nerve branches</p> <p>13 at the same time.</p> <p>14 Q. Anything abnormal about the nerve</p> <p>15 branches and twigs that you depict in those images?</p> <p>16 A. Just the location.</p> <p>17 Q. Okay. Page 38, "Additional TVT</p> <p>18 cases." What does this show?</p> <p>19 A. The same as it says on the</p> <p>20 previous page, superficial location of the mesh,</p> <p>21 overlying mucosa, innervation of the tissue and the</p> <p>22 mucosa.</p> <p>23 Q. And other than the presence of the</p> <p>24 nerves in the mucosa, and the position of those</p> <p>25 nerves relative to the mesh in the mucosa, is there</p> | <p style="text-align: right;">Page 173</p> <p>1 Q. I'm sorry. That's a southern West</p> <p>2 Virginia way of saying it, I apologize.</p> <p>3 A. Okay. So there is dilatation of</p> <p>4 the vascular structure, blood stays in. If it's</p> <p>5 lymphatic vessel, lymph will stay, so it will</p> <p>6 distend and it becomes larger.</p> <p>7 Q. Now, what is stasis, S-T-A-T-I-S?</p> <p>8 A. Stasis, sorry.</p> <p>9 Q. Stasis. So stasis and tissue</p> <p>10 edema; what does that mean?</p> <p>11 A. Stasis means that the fluid is</p> <p>12 stagnant in the vessels. So it accumulates there,</p> <p>13 it doesn't outflow. And then after some time, this</p> <p>14 fluid starts seeping into the tissue. So because</p> <p>15 the blood vessels, or lymphatics are so backed up,</p> <p>16 fluid starts going into the tissue; that's how</p> <p>17 edema happens.</p> <p>18 Q. Okay. The blue in the image is</p> <p>19 polypropylene?</p> <p>20 A. Yes.</p> <p>21 Q. And that is moved in the image by</p> <p>22 sample preparation?</p> <p>23 A. That's correct.</p> <p>24 Q. The artifacts?</p> <p>25 A. Yes.</p> |

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| <p>1 Q. And do you see any bark around the 2 polypropylene in those images? 3 A. Here. 4 Q. You pointed to the white. I'm 5 looking at the blue polypropylene itself. There's 6 no bark attached to any of the polypropylene, is 7 there? 8 A. Probably there is, but so low 9 magnification. I can see it clearly in this space. 10 Q. And you're referring now to the 11 upper right-hand corner and the black mark at the 12 lower right, correct? 13 A. Just above it -- no, no, here. 14 Q. Are you talking about -- 15 A. The faint line. This faint line. 16 (Indicating). 17 Q. Oh, I see, okay. 18 And what's the clinical significance of 19 the vascular dilatation and stasis tissue edema? 20 A. There's pressure inside. If fluid 21 accumulates to a degree, and then it starts 22 pressing in tissue, there will be pressure 23 accumulating. 24 Q. And to what extent can you 25 determine whether this pressure is present in an</p> | <p>1 Take hemorrhoids, you ask some patients, have them 2 painful; some patients have them not painful. 3 BY MR. THOMAS: 4 Q. I understand that. But it's also 5 fair to understand that this woman may have had 6 this issue in the histology, as you've described 7 it, but not be experiencing any symptoms because of 8 it, correct? 9 A. That's correct. The main thing is 10 it's an abnormal finding and it can cause pain. 11 Q. Okay. Do you know whether the 12 images that are on page 40 are -- 13 A. Stasis. 14 Q. It's the same patient, 6a, 6b? 15 A. Could be, I'm not sure. 16 Q. You don't know, okay. 17 Again, the blue is polypropylene? 18 A. Yes. 19 Q. Are you able to tell in 6b, the 20 long, narrow white space in the lower left hand, 21 whether that is polypropylene that's present or not 22 present? 23 A. I'm not sure. The largest part is 24 difficult. I can see a little bit of the 25 degradation bark can be sitting on the non-degraded</p> |
| Page 175 | Page 177 |
| <p>1 area larger than what is presented in this one 2 slide? 3 A. What do you mean? 4 Q. Well, this obviously depicts these 5 findings within this slide. This slide is 6 4 microns thick, and I don't know how far across. 7 A. About two and a half, three 8 millimeters. 9 Q. Okay. Can you tell whether this 10 finding is present anywhere else in the woman from 11 which this was explanted? 12 A. Oh, it's patches. Somewhere it's 13 dilated, some areas are edematous, some are not. 14 Sometime the entire mesh is just sewed, or is shown 15 edema or dilatation. It depends, variables. 16 Q. And so you're unable to say, 17 looking at this figure on page 39, Figure Set 6a, 18 whether what you've described here was causing 19 symptoms in this woman, correct? 20 MR. ORENT: Objection. 21 THE WITNESS: Oh, I think we talked 22 about this before. Causing symptoms is a complex 23 process, and perceptions. 24 So this is abnormal mechanism, it is a 25 factor in pain mechanisms in some other areas.</p> | <p>1 bark and -- oh, I can see some of the mesh fibers 2 left here in this space. 3 Q. Okay. I'm looking at the area 4 above that one, though. This one (indicating). 5 A. Yes, it's folded and it trapped 6 some of the dye. 7 Q. Now how do you know that's folded 8 as opposed to just mesh, part of the interstitialcy 9 or part of the mesh being right adjacent to it? 10 A. Do you see this line, or this 11 slice, or cross-section of the fiber, it's folded 12 like this, and then there's a little bit of a dye 13 in this space, you can see it. 14 Q. So what you're showing here is 15 vascular dilatation stasis again? 16 A. Yes. 17 Q. Tissue edema? 18 A. Yes. 19 Q. Anything else remarkable about 20 this slide? 21 A. No. 22 Q. And the top is four times 23 magnification, and the bottom is ten times 24 magnification? 25 A. That's the best approximation.</p> |

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| <p style="text-align: right;">Page 178</p> <p>1 Q. And my expert should have this 2 slide, correct? 3 A. Yes. 4 Q. Since you did 6a, 6b, 6c, does 5 that mean that it's from the same patient? 6 A. No. They group by the feature. 7 Q. Okay. So you don't look at it? 8 (Reporter sought clarification.) 9 A. Feature. So if it's the same 10 feature, it's the same figure number, but if it's 11 different images on different pages, they are 12 labeled A, B, C, D. 13 Q. What is the significance of the 14 edematous scar; the edema, loose scar? 15 A. It's edema, the same thing we 16 discussed before. The fluid stays in it, it builds 17 up pressure and can compress the structures. 18 Q. The same on page 41, 6c? 19 A. That's correct. 20 Q. Anything remarkable about the 21 image on page 41 beyond what you've described? 22 A. No. 23 MR. ORENT: Counsel, I'm wondering if 24 it's a good time to take a quick lunch break? 25 THE WITNESS: It feels like it.</p> | <p style="text-align: right;">Page 180</p> <p>1 retropubic tapes as well. 2 Q. And what are you showing in Figure 7a? 3 A. I'm showing involvement of 4 striated muscle in the mesh. 5 Q. Tell me what you mean by that. 6 A. Striated muscle can be 7 incorporated right in the mesh, most likely mesh 8 migrated into the striated muscle. Or sometimes 9 it's just attached to it, so the fibrous capsule. 10 Q. On the left side is the actual 11 slide, and on the right side you've filled in with 12 a red, orange and a yellow, correct? 13 A. Yellow and red. 14 Q. Okay. The yellow is the 15 polypropylene? 16 A. That is correct. 17 Q. And the red is what? 18 A. Red is striated muscle. 19 Q. All right. And you said 20 "involvement of striated muscle by the mesh." 21 This shows striated muscle adjacent to, 22 but not incorporated in the mesh, correct? 23 A. Some parts of this incorporated, 24 sometimes it's just been fused, surface scar 25 tissue.</p> |
| <p style="text-align: right;">Page 179</p> <p>1 MR. THOMAS: Sure, absolutely. 2 -- OFF THE RECORD DISCUSSION -- 3 -- RECESS AT 1:01 -- 4 -- UPON RESUMING AT 2:11 -- 5 BY MR. THOMAS: 6 Q. Let's go to page 42 of your 7 report, please. I see you're open to it already. 8 A. Um-hum. 9 Q. Figure 7a says, "Involvement of 10 striated muscle by the mesh, H&E, 4 times. 11 Additional TVT cases." 12 Again, this is a case that is not 13 contained within the consolidated cases? 14 A. That is correct. 15 Q. Can you tell whether this is 16 TVT or TVT-O? 17 A. No. 18 Q. Does the fact that it's involved 19 striated muscle help you at all? 20 A. To a degree. 21 Q. Why would that influence which 22 kind of mesh it is? 23 A. It helps, because most frequently 24 if I see striated muscle, it's transobturator tape, 25 but occasionally I see striated muscle in</p> | <p style="text-align: right;">Page 181</p> <p>1 Q. Help me. Show me where it's 2 incorporated in it. 3 A. Well, in this case -- 4 Q. You're referring to the lower 5 right? 6 A. In the lower panel, striated 7 muscle is encircling one of the mesh fibers. 8 Q. Okay. What's the distance, in 9 four times magnification from the muscle and the 10 mesh? 11 A. Within 1 to 2 hundred microns, 12 probably 100. 13 Q. Okay. And what's the significance 14 of that finding to your opinions in this case? 15 A. Well, if the mesh is fused with 16 the striated muscle, any contraction of the muscle 17 will tug on the mesh and prevent muscle from free 18 contraction. 19 Q. And what symptoms does that create? 20 A. The mesh is tugged, and you can 21 feel the mesh moving, pulling the nerves and other 22 tissues. So it's related to discomfort, feeling of 23 pressure and pain. 24 Q. Once again, is it true that you 25 can't say by looking at the images in 7a, that this</p> |

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| <p>1 patient was experiencing pain or discomfort due to</p> <p>2 the presence of the striated muscle next to the</p> <p>3 polypropylene mesh?</p> <p>4 A. I cannot say the degree of</p> <p>5 sensation, but in this specific location, any</p> <p>6 contraction of the muscle will tug on the mesh. So</p> <p>7 there will be a degree of sensation, to what degree</p> <p>8 I cannot say.</p> <p>9 Q. All right. Anything else</p> <p>10 remarkable about the images on 42?</p> <p>11 A. No. Just striated muscle</p> <p>12 involvement by the mesh.</p> <p>13 Q. So let's go to Figure 7b on</p> <p>14 page 43. You're using a different stain here, the</p> <p>15 desmin stain.</p> <p>16 A. That is correct.</p> <p>17 Q. What is the significance of Figure</p> <p>18 Set 7b on page 43 of your report?</p> <p>19 A. Clearly, more visible in the</p> <p>20 picture.</p> <p>21 Q. What is more visible?</p> <p>22 A. Striated muscle.</p> <p>23 Q. And that's yellow in this image?</p> <p>24 A. No, brown. Brown is striated</p> <p>25 muscle.</p> | <p>1 would be a tugging, discomfort and possible pain?</p> <p>2 A. That is correct.</p> <p>3 Q. But you don't know the extent to</p> <p>4 which those may manifest themselves from this</p> <p>5 figure?</p> <p>6 A. The degree of sensation is</p> <p>7 difficult to predict, it depends on multiple</p> <p>8 factors.</p> <p>9 I mean, it's clear that in this</p> <p>10 location striated muscle contraction will be</p> <p>11 restricted, and will cause movement of the mesh.</p> <p>12 But the degree of sensation cannot be determined.</p> <p>13 Q. What about page 44? Sorry, let's</p> <p>14 go back to 43.</p> <p>15 Did that cover the remarkable findings</p> <p>16 in Figure 7b?</p> <p>17 A. No, I mean --</p> <p>18 Q. Is there anything else remarkable</p> <p>19 about this?</p> <p>20 A. We've covered everything.</p> <p>21 Q. Thank you. Figure 8a, on page 44.</p> <p>22 A. Yes.</p> <p>23 Q. "Involvement of smooth muscle by</p> <p>24 the mesh, H&E, 10 times. Consolidated cases."</p> <p>25 Are you able to tell me whether this is</p> |
| Page 183 | Page 185 |
| <p>1 Q. Brown, I'm sorry.</p> <p>2 A. Because for a non-pathologist, it</p> <p>3 would be hard to see where striated muscle is in</p> <p>4 H&E section, but when we use desmin stain, it</p> <p>5 demonstrates even the presence of striated muscle.</p> <p>6 Q. I see. Are you able to tell me</p> <p>7 whether the image in 7b is from the same patient as</p> <p>8 the image in 7a?</p> <p>9 A. No, likely not.</p> <p>10 Q. Why do you say that?</p> <p>11 A. Just my recollection.</p> <p>12 Q. Are you able to tell me from what</p> <p>13 patient 7b comes from?</p> <p>14 A. I may or may not.</p> <p>15 Q. How about 7a, do you know who that</p> <p>16 came from?</p> <p>17 A. Same thing, I may or may not.</p> <p>18 Q. Okay. Tell me, please, the</p> <p>19 significance of the image in 7b.</p> <p>20 A. Now, we can see clearly that</p> <p>21 muscle is on both sides of the mesh. So the mesh</p> <p>22 is sandwiched between striated muscle, surrounded</p> <p>23 by it.</p> <p>24 Q. The same answers for 7b as 7a,</p> <p>25 that when the striated muscles touch the mesh there</p> | <p>1 a TVT or TVT-O?</p> <p>2 A. No.</p> <p>3 Q. Okay. And you can't tell me which</p> <p>4 patient it's from as you sit here?</p> <p>5 A. I can determine for this specific</p> <p>6 figures which patient it came from, because this</p> <p>7 image has been numbered by this time.</p> <p>8 Q. And can you tell right now, or do</p> <p>9 you have to consult something?</p> <p>10 A. No, no. I would have to go back</p> <p>11 and check the names of the files.</p> <p>12 Q. I see, okay.</p> <p>13 And what's the purpose of depicting the</p> <p>14 smooth muscle in this image?</p> <p>15 A. To show that smooth muscle can</p> <p>16 also be involved by the mesh.</p> <p>17 Q. Is the smooth muscle impacted in</p> <p>18 the same way as the striated muscle that you</p> <p>19 described in the last two slides?</p> <p>20 A. In a similar way, yes.</p> <p>21 Q. Okay. Is the point here to show</p> <p>22 that the smooth muscle is in close proximity to the</p> <p>23 polypropylene mesh?</p> <p>24 A. That's correct.</p> <p>25 Q. And similar to 7a and 7b, any</p> |

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| <p>1 contact with polypropylene with the smooth muscle 2 may cause some discomfort, tugging or possible 3 pain? 4 A. There is a little bit more to 5 smooth muscle. Because smooth muscle is present in 6 both vaginal wall and urethra and bladder. 7 So urethra and bladder have thicker 8 bundles of smooth muscle. Vaginal wall has wisps 9 of smooth muscle. 10 If mesh is in the vaginal wall, smooth 11 muscle, which is in the vaginal wall, can be either 12 attached to the scar plate. Or, if the mesh 13 migrates, it incorporates smooth muscle inside the 14 pores. 15 So if the smooth muscle of the vaginal 16 wall contracts, the mesh will interfere. So this 17 will be more of a sensation in the vagina, more 18 likely during intercourse, whether the vaginal wall 19 contracts. 20 Now, if we compare it with the smooth 21 muscle of the bladder and the urethra, it's a 22 different organ. So if mesh is interfering with 23 those bundles, they may not contract correctly. So 24 there may be interference with the function of 25 urethra and voiding, urination. And also,</p> | <p>1 Q. Adjacent to? 2 A. Moving, or pressing against this 3 bundle. It's partially compressed; you see the 4 indentation made with the mesh here. 5 Q. Okay. And again, you don't know 6 the extent to which the situation, circumstances 7 described in this slide, may cause or contribute to 8 discomfort, tugging or pain? 9 A. If it's urethral muscle, it can 10 cause urinary outflow obstruction, because it's 11 clearly pressing on this part of the muscle. So 12 it's pressing on the whole urethra. 13 Q. But you don't know the extent to 14 which it was removed for obstruction, or why the 15 mesh was removed; do you? 16 MR. ORENT: Objection. 17 THE WITNESS: Yeah. Again the degree 18 of the symptoms would depend on many factors. I 19 can say that this picture shows that there was a 20 degree of compression of the muscle. 21 BY MR. THOMAS: 22 Q. Can you say from this slide, that 23 there was urinary dysfunction based upon this 24 slide? 25 A. Complete obstruction of the</p> |
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| <p>1 sensation in the area. 2 Also, you should obstruct urethra 3 through compression of it. The mesh is pressing 4 against these thick bundles, and then compresses 5 the urethra. So it's indication that position of 6 the mesh was such that it was causing urinary 7 symptoms. 8 Q. Are you able to tell from Figure 9 8a, whether this tissue sample is from the vagina 10 or in the area underneath the urethra? 11 A. For Figure 8a, it would be 12 difficult because it's an H&E slide. If I stain it 13 with smooth muscle, then I can see exactly borders 14 and position of the muscle. Or, I can see it in 15 the microscope. 16 It's likely to be urethra, because the 17 area is more compact and there are bundles of it, 18 but I would have to look at the slide. But 19 comparing between these two applications, I would 20 favor the urethral muscle in this specific image. 21 Q. And it's fair to say that the 22 muscle here has not yet been incorporated into the 23 mesh, correct? 24 A. Not fully, but you can see that 25 the mesh is --</p> | <p>1 urinary outflow, no, I cannot say that. I mean 2 there is interference, but the degree of it is more 3 complex question. 4 Q. Page 45, Figure Set 8b is the same 5 issue using a smooth muscle actin stain. And 6 because this is additional TVT cases, this is going 7 to be a different patient than 8a, correct? 8 A. That's correct. 9 Q. Is this a TVT or a TVT-O? 10 A. I cannot say. 11 Q. And is this the smooth muscle 12 stain that you referred to a few minutes ago? 13 A. That's correct. 14 Q. And what does the stain in Figure 15 Set 8b tell you? 16 A. So you can see clearly that the 17 smooth muscle is in wisps. So this is the smooth 18 muscle of vaginal wall, and it became incorporated 19 into the mesh. 20 So the mesh migrated in the tissue, and 21 this part of smooth muscle became incorporated in 22 the mesh pore. 23 Q. How can you tell from Figure 8b 24 that the mesh migrated or moved? 25 A. Because it contains normal structure.</p> |

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| <p style="text-align: right;">Page 190</p> <p>1 Q. How does this figure -- how are 2 you able to tell from this figure that the mesh 3 wasn't placed there in the first place, as opposed 4 to migrated or moved there? 5 A. This space didn't exist before the 6 mesh was placed (indicating). 7 Q. Okay. And "this space" is what 8 you just drew as a circle? 9 A. Yes. 10 Q. And what does that space represent? 11 A. It's the space within the mesh. 12 So it was created in the body, when the mesh was 13 placed. When the mesh was placed, it's empty space 14 because tissue is disrupted. The mesh goes in, and 15 everything inside needs to be filled in with brand 16 new tissue. So this area was filled with tissue 17 after the mesh was placed. 18 But, we know that smooth muscle is a 19 more specialized type of tissue. It has very 20 limited ability for regeneration, so the scar which 21 can be produced. So if there is normal tissue 22 within the mesh pore, it means that it had been 23 incorporated later on, either through scar 24 contraction, which pulls normal tissue in, or 25 through mesh migration, which migrates into this</p> | <p style="text-align: right;">Page 192</p> <p>1 about? 2 A. That's correct. 3 Q. Anything else remarkable about 45? 4 A. No. 5 Q. 46, Figure Set 8c. 6 Again, this is more smooth muscle with 7 smooth muscle actin stain, additional TVT cases. 8 Is this a third patient, do you know? 9 A. This is an older case. 10 Q. So is this a third patient within 11 this set? 12 A. Most likely. 13 Q. And it's an older case given the 14 camera that's used? 15 A. Yes. 16 Q. Can you tell whether it's a TVT or 17 TVT-O? 18 A. No. 19 Q. What is the significance of Figure 8c? 20 A. This is a nice picture, this is 21 urethral wall. 22 Q. You're talking about the muscle on 23 the right side of the image on the left? 24 A. Yup. 25 Q. Okay.</p> |
| <p style="text-align: right;">Page 191</p> <p>1 (indicating). 2 Q. What types of symptoms are present 3 from the findings that you have in Figure Set 8b? 4 A. I don't remember exact history for 5 this specific patient, but this position of smooth 6 muscle inside the mesh, is at risk for pain, 7 especially during intercourse, dyspareunia. Again, 8 the degree of these symptoms is difficult to 9 predict. But this is an abnormal position of 10 smooth muscle. 11 Q. Are you suggesting that every time 12 this patient would have sexual intercourse, that 13 she experienced pain due to this condition? 14 MR. ORENT: Objection. 15 THE WITNESS: How much of this will 16 contribute to her symptoms would be difficult to 17 predict. But as I said, this is an abnormal 18 position, and this abnormality provides a risk 19 factor for pain during intercourse. 20 BY MR. THOMAS: 21 Q. Okay. 22 A. Or just simply chronic pain. 23 Q. So as we've talked about before, 24 this is a risk factor in conjunction with other 25 things that may cause the conditions you're talking</p> | <p style="text-align: right;">Page 193</p> <p>1 A. It's a thicker bundles of urethra, 2 and this part is vaginal wall. So this is part of 3 vaginal wall. And you can see the curve of the 4 sling was compressing urethra (indicating). 5 So this part of the sling was excised 6 with some of the urethral muscle. 7 Q. What is the significance of this 8 finding in this figure? 9 A. It shows the difference between 10 smooth muscle in the vaginal wall and smooth muscle 11 in the urethra, and the relationship of the mesh, 12 how it sits right on the muscle of the urethra. 13 Q. If you look at this, as it's going 14 to be in-situ, is it going to look like this? 15 A. Eventually it will look like this. 16 Q. So this is the urethral muscle, 17 and I'm holding Figure 8 sideways. So this shows 18 how the mesh has either the U-shape or the hammock 19 shape underneath the urethra; correct? 20 A. That is correct. 21 Q. Okay. So the positioning of this 22 mesh is really consistent with the way it should be 23 placed; is that correct? 24 A. It's the normal position. It's 25 not normal, intended position.</p> |

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| <p>1 Q. Intended position, okay.</p> <p>2 So what is significant about Figure 8c,</p> <p>3 insofar as it relates to your opinions in this</p> <p>4 case?</p> <p>5 A. Well, I'm demonstrating that the</p> <p>6 mesh is compressing right against urethra. And if</p> <p>7 it was more pressure, it would start migrating into</p> <p>8 urethra and sometimes I see that as well.</p> <p>9 Q. When you say migrating, are you</p> <p>10 talking about eroding into the urethra?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. There's no evidence here,</p> <p>13 though, of evidence of erosion into the urethra,</p> <p>14 correct?</p> <p>15 A. In this specific case, I don't</p> <p>16 remember.</p> <p>17 Q. Well, you don't see it in the</p> <p>18 slide. You can't offer the opinion to a reasonable</p> <p>19 degree of medical certainty that this mesh has</p> <p>20 eroded into the urethra here, correct?</p> <p>21 MR. ORENT: Objection.</p> <p>22 THE WITNESS: Not in this image. And</p> <p>23 the purpose of this different.</p> <p>24 So you can see clearly, I should have</p> <p>25 probably turned it. I should have turned it like</p> | <p>1 that slings can cause urinary outflow and</p> <p>2 obstruction.</p> <p>3 And with more pressure, it will start</p> <p>4 going through the muscle and become eroded. Also,</p> <p>5 it will describe the clinical phenomena.</p> <p>6 Q. And when you talk about disrupting</p> <p>7 urinary outflow, is that the same thing as</p> <p>8 retention?</p> <p>9 A. Yes.</p> <p>10 Q. And that's a recognized complication</p> <p>11 from mesh placement?</p> <p>12 A. Yes, it is.</p> <p>13 Q. Anything else remarkable about</p> <p>14 this slide?</p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Is it fair to understand that</p> <p>19 you're not able to diagnose urinary retention based</p> <p>20 upon this single slide, correct?</p> <p>21 A. Retention is a symptom, as we've</p> <p>22 discussed before, symptoms are caused by multiple</p> <p>23 factors together, so...</p> <p>24 Q. Answer my question. Based on this</p> <p>25 slide alone, you can't make that finding?</p> |
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| <p>1 this (indicating). And this would demonstrate that</p> <p>2 with more pressure, it would start migrating; in</p> <p>3 this specific case, it didn't.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Isn't this supposed to be right</p> <p>6 underneath the urethra in order to control the</p> <p>7 urine flow?</p> <p>8 A. Yes, but I mean --</p> <p>9 Q. Is this not placed properly?</p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: I wouldn't go and I</p> <p>12 cannot testify exactly for placement.</p> <p>13 To me, as a pathologist, I examine what</p> <p>14 is abnormal and what can cause symptoms.</p> <p>15 So if there are specific requirements</p> <p>16 for placement or positioning, it would be a</p> <p>17 clinical question.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. Okay.</p> <p>20 A. So to me, this position, right</p> <p>21 against smooth muscle of urethra, indicates that</p> <p>22 sling is compressing against urethra directly.</p> <p>23 So, with extra pressure, you can</p> <p>24 collapse or compress urethra and cause urinary</p> <p>25 outflow. And this is repeated in medical histories</p> | <p>1 A. You can say that this position</p> <p>2 creates a risk for obstruction.</p> <p>3 Q. Yeah.</p> <p>4 A. And a degree of compression of the</p> <p>5 urethra.</p> <p>6 Q. But like everything else, that's a</p> <p>7 risk factor that you'd have to combine with other</p> <p>8 things to determine whether, and to what extent</p> <p>9 this could cause any problems in her, right?</p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: Not necessarily. It may</p> <p>12 not need other factors. It may cause symptom on</p> <p>13 its own. But the degree of the symptom is clinical</p> <p>14 presentation.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. And you don't know what that</p> <p>17 clinical presentation is as you sit here today?</p> <p>18 A. That's correct.</p> <p>19 Q. Page 47, Figure 8d. This is,</p> <p>20 "Innervation within the mesh and between the mucosa</p> <p>21 and the mesh. Also, images of muscle movement</p> <p>22 involvement by the mesh." And this is a</p> <p>23 publication?</p> <p>24 A. That's correct.</p> <p>25 Q. Do you know what kinds of mesh are</p> |

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| <p>1 involved here?</p> <p>2 A. I don't remember. I think two of</p> <p>3 these images are from TVT or TVT-O. And two of</p> <p>4 these images are from different mesh.</p> <p>5 Q. Which ones are from TVT or TVT-O?</p> <p>6 A. I don't remember now. I would</p> <p>7 have to sort of do matching.</p> <p>8 Q. Okay. What other manufacturers</p> <p>9 did you look at?</p> <p>10 A. AMS, Boston Scientific, Bard.</p> <p>11 Q. And do you know which of those</p> <p>12 manufacturers are depicted in this image?</p> <p>13 A. No, I know for sure that there's</p> <p>14 at least one TVT mesh here.</p> <p>15 Q. At least one?</p> <p>16 A. At least one. I don't remember --</p> <p>17 Q. Do you know whether it was a TVT</p> <p>18 or a TVT-O?</p> <p>19 A. No.</p> <p>20 Q. Okay. And what is the purpose of</p> <p>21 this image?</p> <p>22 A. It demonstrates same smooth muscle</p> <p>23 involvement.</p> <p>24 Q. Are you able to tell -- as I</p> <p>25 understand the smooth muscle is either going to be</p> | <p>1 two or both (indicating).</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Okay. C and D, correct?</p> <p>4 A. C and D. That is my recollection.</p> <p>5 Q. What is it about those images that</p> <p>6 cause you to believe it's an Ethicon TVT or TVT-O?</p> <p>7 A. Oh, maybe not. Wait a second.</p> <p>8 (Witness reviews document).</p> <p>9 Sorry. I have to retry this. I don't</p> <p>10 remember which exactly are TVT or TVT-O. It could</p> <p>11 be one of these images in one of these.</p> <p>12 Q. It could be any one of the four?</p> <p>13 MR. ORENT: Objection.</p> <p>14 THE WITNESS: Yes, I would have to go</p> <p>15 back and check.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Now this is smooth muscle; is that</p> <p>18 what you're saying?</p> <p>19 A. These are smooth muscle.</p> <p>20 Q. In A, B, C and D?</p> <p>21 A. No. Figure A shows neurovascular</p> <p>22 bundle in the pore, we saw similar images before</p> <p>23 that.</p> <p>24 Figure B shows innervation between</p> <p>25 sling and mucosa.</p> |
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| <p>1 in the vagina or around the urethra, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Are you able to tell in Figure 8</p> <p>4 whether this is the vagina or the urethra?</p> <p>5 A. Let me see, because the pictures</p> <p>6 are cropped to a degree.</p> <p>7 Q. They're "cropped", did you say?</p> <p>8 A. Cropped, yes. So I need the</p> <p>9 larger pictures to -- let me see.</p> <p>10 Maybe it's described in the caption.</p> <p>11 (Witness reviews document.)</p> <p>12 Just representative image. From what I</p> <p>13 see, but it's not 100 percent, it may not be</p> <p>14 100 percent correct.</p> <p>15 C, would reflect urethral muscle. And</p> <p>16 D would reflect vaginal muscle. But I'm not sure,</p> <p>17 because most of the structures are cropped. It</p> <p>18 just describes the fact that the mesh can</p> <p>19 incorporate smooth muscle, from either origin.</p> <p>20 Q. And just so we're clear. You're</p> <p>21 pretty sure that one of these is a TVT or a TVT-O,</p> <p>22 but you don't know which of the four figures in</p> <p>23 Figure Set 8d is a Johnson & Johnson product?</p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: It would be either these</p> | <p>1 Figure C -- (witness reviews document.)</p> <p>2 Q. Are you reading the text now?</p> <p>3 A. Yes. So Figure C shows striated</p> <p>4 muscle.</p> <p>5 And Figure D, shows smooth muscle</p> <p>6 unspecified, either from vagina or urethra.</p> <p>7 Q. Okay. And is the purpose of this</p> <p>8 image just to show the innervation of the mesh in</p> <p>9 general?</p> <p>10 A. Well, the purpose of the image is</p> <p>11 to show all these pictures together. And I</p> <p>12 included it because I knew that at least one</p> <p>13 contains TVT or TVT-O, it is a supplementary</p> <p>14 picture.</p> <p>15 Q. Anything else significance for the</p> <p>16 figures on page 47?</p> <p>17 A. No.</p> <p>18 Q. Page 48, Figure Set 9a. "Arterial</p> <p>19 obliteration in the mesh scar plate, H&E 10 times.</p> <p>20 Consolidated cases."</p> <p>21 This obviously is from one of the</p> <p>22 plaintiffs in the consolidated cases.</p> <p>23 A. Yes.</p> <p>24 Q. And you've indicated on the image</p> <p>25 an obliterated artery. How can you -- what is it</p> |

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| <p>1 about this image that tells you that this artery is</p> <p>2 obliterated?</p> <p>3 A. The lumen is collapsed.</p> <p>4 Q. The lumen is collapsed?</p> <p>5 A. Yes. The arterial wall is</p> <p>6 degenerated, so clearly non-functional.</p> <p>7 Q. And what does it mean to have an</p> <p>8 obliterated artery?</p> <p>9 A. It means that there is an area in</p> <p>10 the body which had insufficient or disrupted blood</p> <p>11 supply.</p> <p>12 Q. Okay. When you say "insufficient</p> <p>13 or disrupted", it can be disrupted without being</p> <p>14 insufficient; can't it?</p> <p>15 A. That's correct. There might be a</p> <p>16 collateral circulation sufficient to supply.</p> <p>17 Q. And you're not able to tell from</p> <p>18 looking at this image in Figure Set 9a, that if</p> <p>19 this is an obliterated artery, that it has any</p> <p>20 clinical impact on the patient, correct?</p> <p>21 MR. ORENT: Objection.</p> <p>22 THE WITNESS: Again, could have had</p> <p>23 only short-term impact, could have had longer term</p> <p>24 impact. Short term would be necrosis, right after</p> <p>25 the obliteration, or thrombosis, it's like heart</p> | <p>1 MR. ORENT: Objection.</p> <p>2 THE WITNESS: Not in this area.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. Okay.</p> <p>5 A. But it tells us that somewhere</p> <p>6 else beyond this square picture, there was damage</p> <p>7 for the tissue.</p> <p>8 Q. There was or may be?</p> <p>9 A. There was.</p> <p>10 Q. Okay.</p> <p>11 A. The degree of it is difficult to</p> <p>12 determine. But there was.</p> <p>13 Q. You'd have to see the tissue in</p> <p>14 order to make that evaluation, correct?</p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Where is the mesh in Figure 9a?</p> <p>19 A. Somewhere beyond it.</p> <p>20 Q. It's not in the slide?</p> <p>21 A. Maybe right at the corners, I</p> <p>22 don't know.</p> <p>23 Q. But you didn't capture any mesh in</p> <p>24 the slide on 9a?</p> <p>25 A. I didn't crop it in.</p> |
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| <p>1 attack.</p> <p>2 And then long-term would be scarring</p> <p>3 and fibrosis. The same thing as a heart, people</p> <p>4 who have insufficient cardiac output. If heart</p> <p>5 muscle doesn't work as well as before the infarct,</p> <p>6 so the same thing here, it would be a short term,</p> <p>7 shortly symptoms or changes in the body. And then</p> <p>8 longer term. Longer term would be caused more</p> <p>9 fibrosis.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. And longer term there may or may</p> <p>12 not be a problem, correct?</p> <p>13 A. You mean how they would translate</p> <p>14 into clinical symptoms?</p> <p>15 Q. Yes.</p> <p>16 A. The degree of translation into</p> <p>17 clinical symptoms is more a complex process.</p> <p>18 Q. Okay. Is there necrosis in this</p> <p>19 image?</p> <p>20 A. No. Because artery has supplied</p> <p>21 the blood to somewhere else further down, so...</p> <p>22 Q. Okay. So given your finding of an</p> <p>23 obliterated artery, there are no clinical symptoms</p> <p>24 manifested in this image, at this time that you can</p> <p>25 point to, correct?</p> | <p>1 Q. Let's go to page 49, Figure Set 9b.</p> <p>2 A. Yes.</p> <p>3 Q. It says, "Examples of capillary</p> <p>4 thrombosis in the mesh scar plate."</p> <p>5 What is "capillary thrombosis"?</p> <p>6 A. When there are small thrombi</p> <p>7 formed in the capillaries.</p> <p>8 Q. What is the significance of</p> <p>9 capillary thrombosis in the mesh scar plate?</p> <p>10 A. The same as for arteries, just on</p> <p>11 a small scale. So there's interruption of blood</p> <p>12 supply in the smaller area. Artery can cover large</p> <p>13 area, capillaries are covering small.</p> <p>14 Q. Is there anything about what you</p> <p>15 see in Figure Set 9b, that would tell you that this</p> <p>16 patient is experiencing any clinical symptoms?</p> <p>17 A. Again, the degree of manifestation</p> <p>18 of this finding would be difficult to determine.</p> <p>19 Q. It could be nothing?</p> <p>20 A. May not be clinically apparent.</p> <p>21 Q. And is this a single plaintiff or</p> <p>22 is it two different plaintiffs? It says,</p> <p>23 "additional TVT cases." I can't tell if it's one</p> <p>24 patient or two.</p> <p>25 A. I think it's from the same patient.</p> |

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| <p>1 Q. Is it a TVT or TVT-O?</p> <p>2 A. I think it was the Edwards case.</p> <p>3 That's as far as I can recollect.</p> <p>4 Q. Okay. Is there any mesh in Figure</p> <p>5 Set 9b?</p> <p>6 A. Right there (indicating).</p> <p>7 Q. So that's on the lower left, okay.</p> <p>8 Is there any mesh in the image above?</p> <p>9 A. Not in the image. It was probably</p> <p>10 right beside it.</p> <p>11 Q. Okay. Let's go to Figure Set 10a</p> <p>12 on page 50. It says, "TVT sling curled into a roll</p> <p>13 cross-section through parallel walls. H&E stain</p> <p>14 2.5 power magnification. Consolidated cases."</p> <p>15 This shows a piece of curled mesh,</p> <p>16 doesn't it?</p> <p>17 A. That is correct.</p> <p>18 Q. And this is the curled mesh that</p> <p>19 you talked about before when you place it in</p> <p>20 formalin that it will curl over on itself, correct?</p> <p>21 When it's placed in formalin?</p> <p>22 A. Did I say that it curls in</p> <p>23 formalin? I said that mesh, which is curled in</p> <p>24 scar tissue, curled in the body.</p> <p>25 Q. I see. So you believe that this</p> | <p>1 obviously has been pulled away from the slide,</p> <p>2 correct?</p> <p>3 A. That's correct.</p> <p>4 Q. That's polypropylene?</p> <p>5 A. That's correct.</p> <p>6 Q. Let's go to set 10b. Is set 10b</p> <p>7 from the same patient or a different patient?</p> <p>8 A. I suspect it is the same patient.</p> <p>9 Q. Do you know?</p> <p>10 A. Not with 100 percent certainty.</p> <p>11 But I think it is. It's just a different part the</p> <p>12 of the same curled mesh.</p> <p>13 Q. Okay. And does Figure Set</p> <p>14 10b show anything new beyond what you've showed in</p> <p>15 10a, or is it the same?</p> <p>16 A. It's the same, just tighter roll.</p> <p>17 Q. And if you look at the images at</p> <p>18 the top, there's a blue line coming out of the top</p> <p>19 right, and that's a polypropylene artifact?</p> <p>20 A. Displaced polypropylene fibers.</p> <p>21 You can also see dilated vascular channels.</p> <p>22 (Reporter sought clarification.)</p> <p>23 A. So in this area, there is vascular</p> <p>24 dilation.</p> <p>25 Q. Can you tell from these images,</p> |
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| <p>1 curled in the body?</p> <p>2 A. Yes.</p> <p>3 Q. And on what basis do you believe</p> <p>4 that?</p> <p>5 A. Because that curl shape is</p> <p>6 immobilized within the scar tissue, it's</p> <p>7 incorporated in the scar tissue, in this shape.</p> <p>8 Q. Okay. Anything other than the</p> <p>9 curling phenomena that you've just described as the</p> <p>10 purpose of Figure Set 10a?</p> <p>11 A. Curling phenomena, scarring, it's</p> <p>12 all encased in scar tissue.</p> <p>13 Q. Okay.</p> <p>14 A. That's about it.</p> <p>15 Q. Okay. And at the top where we see</p> <p>16 the blue, those are going to be artifacts?</p> <p>17 A. No. The blue ones are</p> <p>18 cross-sections of the blue filaments.</p> <p>19 Q. I should have said, in places</p> <p>20 where they don't fill the holes?</p> <p>21 A. It can't be clear filament.</p> <p>22 Because remember, half of the fibers in the sling</p> <p>23 are blue, half of them are clear.</p> <p>24 Q. Okay. Let's look at the top, off</p> <p>25 of the slide there is a blue fragment. That</p> | <p>1 10a and 10b, whether this mesh caused any symptoms</p> <p>2 in the patient when it was implanted?</p> <p>3 MR. ORENT: Objection.</p> <p>4 THE WITNESS: My answer is the same.</p> <p>5 Clinical symptoms is a multifactorial, complex</p> <p>6 phenomena.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. This is a risk factor?</p> <p>9 A. No, this is not a risk factor,</p> <p>10 this is a mechanism, how the complications occur.</p> <p>11 But then there is a patient in between</p> <p>12 who feels the symptoms, and the body however reacts</p> <p>13 and so forth. But in this case, the mesh is</p> <p>14 rolled, so the pressure is distributed in a small</p> <p>15 area.</p> <p>16 The probability that it will compress</p> <p>17 urethra is higher, because if it was flat, it would</p> <p>18 have much larger distribution of pressure.</p> <p>19 Q. So is the risks from this curl</p> <p>20 mesh compression against the urethra and urinary</p> <p>21 retention?</p> <p>22 A. Yes, one of those.</p> <p>23 Q. Do you know whether this patient</p> <p>24 had urinary retention?</p> <p>25 MR. ORENT: Objection.</p> |

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| Page 210 | Page 212 |
|--|---|
| <p>1 THE WITNESS: I don't remember now.</p> <p>2 Because my purpose for this report was to actually</p> <p>3 show these things which can happen, and the</p> <p>4 pathological changes which happen after mesh</p> <p>5 placement.</p> <p>6 And, symptoms which can factor in.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Okay.</p> <p>9 A. But I wasn't working on specific</p> <p>10 connection between this pathological change, caused</p> <p>11 that symptom in this specific patient.</p> <p>12 Q. Okay. Anything else remarkable</p> <p>13 about the images on 50 and 51?</p> <p>14 A. No.</p> <p>15 Q. Go to page 52. And you get</p> <p>16 "Neurovascular bundle within curled mesh, four</p> <p>17 times magnification. Consolidated cases."</p> <p>18 Is this a different patient than was</p> <p>19 depicted in 10a and 10b?</p> <p>20 A. One of these, because I say that</p> <p>21 it's curled mesh --</p> <p>22 (Witness reviews document).</p> <p>23 So likely it was one of these two.</p> <p>24 Q. I think you told me -- well, maybe</p> <p>25 I didn't hear this right. I thought you told me</p> | <p>1 talk about flat mesh, it's sort of third dimension.</p> <p>2 So compartments are within the thickness of the</p> <p>3 mesh. But when it curls, it creates secondary</p> <p>4 compartment. Compartment which is encircled by the</p> <p>5 mesh or between the folds.</p> <p>6 Q. Anything that you can see in</p> <p>7 Figure 10c, on page 52 that is abnormal or</p> <p>8 symptomatic about that neurovascular bundle, other</p> <p>9 than its presence in the scar tissue?</p> <p>10 A. It's abnormal location.</p> <p>11 Q. It's simply that, the abnormal</p> <p>12 location?</p> <p>13 A. Yes.</p> <p>14 Q. Anything else?</p> <p>15 A. The surroundings are abnormal.</p> <p>16 Q. Okay. Anything else remarkable</p> <p>17 about that image?</p> <p>18 A. No.</p> <p>19 Q. Let's go to page 53, section 10d.</p> <p>20 This is, "A twisted TVT sling" from additional TVT</p> <p>21 cases."</p> <p>22 So this is one of your older cases,</p> <p>23 correct?</p> <p>24 A. Yeah. Earlier or concurrent.</p> <p>25 Q. Is this a TVT or TVT-O?</p> |
| Page 211 | Page 213 |
| <p>1 that A and B were from the same person?</p> <p>2 A. Most likely.</p> <p>3 Q. Do you know?</p> <p>4 A. I can tell you, but not right now.</p> <p>5 I can just check the name of the files.</p> <p>6 Q. And do you think that 10c, is the</p> <p>7 same or different person?</p> <p>8 A. Most likely it is the same person,</p> <p>9 or one of the two. It could all be from one</p> <p>10 patient, it could be from two patients.</p> <p>11 Q. Okay. In the top part on 10c, on</p> <p>12 page 52, you have a displaced piece of</p> <p>13 polypropylene?</p> <p>14 A. Yes.</p> <p>15 Q. And what's the significance of</p> <p>16 identifying this neurovascular bundle in the</p> <p>17 figure?</p> <p>18 A. As before, we were talking about</p> <p>19 entrapment of the neurovascular bundle before. But</p> <p>20 in this case, it's not just in pore. It goes in</p> <p>21 the pore, and became entrapped in the curls.</p> <p>22 So it's in between two layers of the</p> <p>23 mesh right inside the curl. So it's secondary type</p> <p>24 of compartment. Because before we're talking about</p> <p>25 compartmentalizing nature of the mesh, and then we</p> | <p>1 A. I don't know.</p> <p>2 Q. What is the significance of what</p> <p>3 you've done in Figure 10d?</p> <p>4 A. It shows that the mesh just</p> <p>5 curled, and also twisted. To get the shape like</p> <p>6 this out of flat tape, it has to curl and then one</p> <p>7 end is twist.</p> <p>8 Just think about it, how they put these</p> <p>9 sections in this shape. So one end like this, and</p> <p>10 the other one is probably like that (indicating).</p> <p>11 Or maybe like this (indicating).</p> <p>12 Q. Okay. Does that happen by</p> <p>13 placement, or by migration in the body, or do you</p> <p>14 know?</p> <p>15 A. It's hard to figure out if you can</p> <p>16 place it like this.</p> <p>17 Q. Do you know?</p> <p>18 A. I don't know. One thing I can</p> <p>19 tell you, this shape was formed in the body and</p> <p>20 then it became incorporated in scar tissue like</p> <p>21 this.</p> <p>22 Q. But you don't know whether that</p> <p>23 happened on placement or in some other way?</p> <p>24 A. No.</p> <p>25 Q. Okay. Now, in Figure 2 and</p> |

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|---|---|
| <p>1 Figure 3, you show different images of the yellow.</p> <p>2 What's the purpose of doing gradations of the</p> <p>3 yellow?</p> <p>4 A. Well, this shows the planes of the</p> <p>5 mesh. Just to help you to understand that we're</p> <p>6 talking about the mesh which twisted.</p> <p>7 Q. Okay. Figure 10e is explanted</p> <p>8 mesh. This has been in formalin, correct?</p> <p>9 A. Yes. I believe it was in</p> <p>10 formalin.</p> <p>11 Q. Okay. And no attempt to clean it</p> <p>12 at all, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. And the purpose here is to show</p> <p>15 what you believe to be the curling of the mesh?</p> <p>16 A. Well, it's not what I believe. I</p> <p>17 observe curling. It's hard to show in the picture,</p> <p>18 but when you look at it with just magnifying glass</p> <p>19 or if you have good eyes, you can see that the mesh</p> <p>20 is curled up and then it's all filled with scar</p> <p>21 tissue.</p> <p>22 Q. Is the purpose of this just to</p> <p>23 show the simple curling, or are you trying to show</p> <p>24 something beyond other than that?</p> <p>25 A. No, just curling. And that the</p> | <p>1 Q. Is it TVT or TVT-O?</p> <p>2 A. I don't know.</p> <p>3 Q. Does the AMS figure have any</p> <p>4 relevance to your discussion in this case?</p> <p>5 A. Not necessarily, no.</p> <p>6 Q. Okay. Tell me what is significant</p> <p>7 to you about the TVT in part B of set 10f?</p> <p>8 A. See, the images which were taken</p> <p>9 from publications were not cropped, so I don't</p> <p>10 remove any panels. So in this image, I think I had</p> <p>11 a TVT, I provided the entire --</p> <p>12 Q. I understand, that's okay.</p> <p>13 A. So in this case I can tell exactly</p> <p>14 this is TVT, and this is a different manufacturer.</p> <p>15 Q. All right. So what is the</p> <p>16 significance of slide B?</p> <p>17 A. It's curled, it's roped. You can</p> <p>18 see it's not tightly -- it's not flat. It's</p> <p>19 tightly curled.</p> <p>20 Q. Can you tell whether it was placed</p> <p>21 that way or whether that happened after placement?</p> <p>22 MR. ORENT: Objection.</p> <p>23 THE WITNESS: I can't say. The only</p> <p>24 thing I can say is that it happened in the body.</p> <p>25</p> |
| Page 215 | Page 217 |
| <p>1 curled shape is actually filled with scar tissue.</p> <p>2 It's not formalin, as you'd like to say, causing</p> <p>3 the curling. It was removed from the body in that</p> <p>4 shape.</p> <p>5 Q. Can you tell whether, assuming</p> <p>6 this is curled in the body, whether it was curled</p> <p>7 upon placement or curled after placement?</p> <p>8 A. The only thing I can say, it can</p> <p>9 happen, and it happened.</p> <p>10 Q. Okay. But you don't know whether</p> <p>11 it happened during placement or after placement?</p> <p>12 MR. ORENT: Objection.</p> <p>13 THE WITNESS: I don't know.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. If you go to page 55, Figures A</p> <p>16 and B, set 10f. "A TVT sling with curled edges.</p> <p>17 Right sling is TVT."</p> <p>18 Are these two different slings or one;</p> <p>19 do you know?</p> <p>20 A. These are two different slings,</p> <p>21 this is AMS, this one I remember.</p> <p>22 Q. AMS is on the left?</p> <p>23 A. Yes.</p> <p>24 Q. And TVT is on the right?</p> <p>25 A. Yes.</p> | <p>1 BY MR. THOMAS:</p> <p>2 Q. Okay. Anything else remarkable</p> <p>3 about 10f on page 55?</p> <p>4 A. No, just roping.</p> <p>5 Q. Page 56, you have Figure Set</p> <p>6 10f again. Is that a typo, or is that the same</p> <p>7 mesh? It looks like a different mesh, it looks</p> <p>8 like one of yours.</p> <p>9 A. It's a typo.</p> <p>10 Q. So this would be 10f --</p> <p>11 A. No, it should be 10d.</p> <p>12 Q. 10d?</p> <p>13 A. I think it's the same specimen as</p> <p>14 10e.</p> <p>15 Q. Okay.</p> <p>16 A. The same case, I believe. So this</p> <p>17 case took two pieces. One piece was rolled like</p> <p>18 this, like 10e.</p> <p>19 Q. Okay.</p> <p>20 A. And the second piece was flat</p> <p>21 area. Sometimes one piece, especially if it's</p> <p>22 heat-treated doesn't curl. So there is a segment</p> <p>23 of mesh --</p> <p>24 Q. What do you mean heat-treated,</p> <p>25 during removal?</p> |

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|---|--|
| <p>1 A. No, during manufacturing.</p> <p>2 Q. Are you talking about heat-treated</p> <p>3 as in laser cut?</p> <p>4 A. No, the entire surface is</p> <p>5 heat-treated, not just edges.</p> <p>6 Q. And so what impact -- I didn't see</p> <p>7 it anywhere in your report, that heat somehow in</p> <p>8 the manufacturing process will impact the ability</p> <p>9 of the mesh to lay flat in the body?</p> <p>10 A. It doesn't curl -- oh, doesn't</p> <p>11 curl as much.</p> <p>12 Q. Okay.</p> <p>13 A. It's more stable structure because</p> <p>14 fibers are welded together, or to a degree</p> <p>15 connected together.</p> <p>16 Q. Okay.</p> <p>17 A. I know that some of the tapes --</p> <p>18 Q. Some other manufacturers?</p> <p>19 A. Other manufacturers, middle</p> <p>20 portion is heat-treated.</p> <p>21 Q. Okay. So did Boston Scientific</p> <p>22 mention it?</p> <p>23 A. I don't know.</p> <p>24 Q. It's all right.</p> <p>25 A. I don't remember now. I mean some</p> | <p>1 TVT cases?</p> <p>2 A. Yes.</p> <p>3 Q. Has this been produced in a report</p> <p>4 somewhere? I've never seen this image in a case</p> <p>5 anywhere, I'm just curious to know if it's been</p> <p>6 published in a report someplace.</p> <p>7 A. I don't want to disclose that if</p> <p>8 it has not been produced, so it have been produced.</p> <p>9 Q. Let me ask you this. Here is why</p> <p>10 I ask: Generally, as you know, at least with</p> <p>11 Ethicon, we divide these meshes before any work is</p> <p>12 done on them.</p> <p>13 Did you divide this mesh with Ethicon</p> <p>14 before you did this work on 10f?</p> <p>15 A. It could be that was divided with</p> <p>16 your expert, so we were taking pictures together.</p> <p>17 Q. Okay. Well maybe that's right.</p> <p>18 A. I think it was the case. Now I</p> <p>19 can vaguely remember the issue because we were</p> <p>20 discussing how we're going to cut this diagonal or</p> <p>21 cut it --</p> <p>22 Q. I see.</p> <p>23 A. And so I remember him standing</p> <p>24 beside me, and I was taking those pictures.</p> <p>25 Q. I see.</p> |
| Page 219 | Page 221 |
| <p>1 of them were coming out first, with no heat</p> <p>2 treatment, and then later on they became</p> <p>3 heat-treated.</p> <p>4 So some portions don't curl because of</p> <p>5 heat treatment, or just don't curl because of other</p> <p>6 factors. So in this specific case, there was a</p> <p>7 segment of the sling removed, and it was curled.</p> <p>8 And in another segment of the sling removed and it</p> <p>9 remained flat in the body.</p> <p>10 Q. Okay. Do you know why?</p> <p>11 A. No, I don't know. One of the</p> <p>12 reasons can be heat treatment.</p> <p>13 Q. It could also be placement?</p> <p>14 A. It could also be placement or</p> <p>15 location.</p> <p>16 Q. And what is the purpose of the red</p> <p>17 and the yellow on the image on 10f on page 56?</p> <p>18 A. It just demonstrates how flat</p> <p>19 section of the mesh looks, and how a curled section</p> <p>20 of the mesh looks. Because here, cross-section,</p> <p>21 this mesh.</p> <p>22 Q. Yes?</p> <p>23 A. And then it came on histological</p> <p>24 sections like this.</p> <p>25 Q. Is this from a case, additional</p> | <p>1 A. I took this picture, then this</p> <p>2 picture, then we probably have similar pictures</p> <p>3 from him.</p> <p>4 Q. And I apologize, I've been asking</p> <p>5 this question a lot, and I don't know if I've asked</p> <p>6 you about this slide, so if I have, I apologize.</p> <p>7 You don't know whether the curling</p> <p>8 depicted in 10f, on page 56 occurred during</p> <p>9 placement or after placement, do you?</p> <p>10 A. No, I don't.</p> <p>11 MR. ORENT: Objection.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Page 57, Figure Set 10g. "A TVT</p> <p>14 sling with curled edges." Is this a different TVT</p> <p>15 than the ones we've looked at?</p> <p>16 A. I think these are the pictures of</p> <p>17 the same case. Again, that is my recollection, I'm</p> <p>18 not 100 percent sure, but I think.</p> <p>19 Q. Do you know if this is a TVT or a</p> <p>20 TVT-O?</p> <p>21 A. No.</p> <p>22 Q. Are you trying to show anything by</p> <p>23 these images on 10g other than a different</p> <p>24 depiction of what's in 10f?</p> <p>25 A. Well, no. This just shows the</p> |

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| Page 222 | Page 224 |
|---|--|
| <p>1 curling state, this cross-section (indicating).</p> <p>2 Q. Okay. So it's your best</p> <p>3 recollection that the images in 10e, 10f and 10g,</p> <p>4 are from the same mesh, same patient?</p> <p>5 A. Yes, likely than not, these are</p> <p>6 all from the same patient.</p> <p>7 Q. But you're not sure?</p> <p>8 A. No. As I said, the purpose of</p> <p>9 this report was to analyze the device as a whole,</p> <p>10 not the individual patients.</p> <p>11 Q. 10h: "TVT sling with curled</p> <p>12 edges. Additional TVT cases"?</p> <p>13 A. Yes.</p> <p>14 Q. Do you know where -- is this a new</p> <p>15 patient; do you know?</p> <p>16 A. It's older pictures, taken by old</p> <p>17 camera.</p> <p>18 Q. Do you know whether this is a</p> <p>19 TVT or TVT-O?</p> <p>20 A. No.</p> <p>21 Q. What is the purpose of this image?</p> <p>22 A. It show the cross-section of the</p> <p>23 curl. And you can see it clearly, the whole field</p> <p>24 is scar tissue. This indicates that this curl</p> <p>25 shape was formed in the body and then the scar</p> | <p>1 is inside the roll of the curled tape.</p> <p>2 Q. And is there anything about the</p> <p>3 depiction in the neurovascular bundle in set 10i on</p> <p>4 page 59 that is irregular or abnormal other than</p> <p>5 its presence in the scar plate?</p> <p>6 A. Well, it's bent by the mesh fiber,</p> <p>7 you can see clearly that it deviates from straight</p> <p>8 course.</p> <p>9 Q. Anything about that that makes you</p> <p>10 have an opinion that this is causing any symptoms</p> <p>11 in the person who has this mesh?</p> <p>12 MR. ORENT: Objection. Form.</p> <p>13 THE WITNESS: Probably, the nerve is</p> <p>14 irritated by these fibers higher, because it is a</p> <p>15 direct compression on the nerve.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. But there's nothing about this</p> <p>18 slide, just like the other slides, which tells you</p> <p>19 that the neurovascular bundle in Figure Set 10i,</p> <p>20 actually caused symptoms in the person who had this</p> <p>21 mesh?</p> <p>22 MR. ORENT: Objection.</p> <p>23 THE WITNESS: We discuss this before.</p> <p>24 The degree of symptoms, the expression by the</p> <p>25 patient is a complex process.</p> |
| Page 223 | Page 225 |
| <p>1 tissue growing inside and filled the two-block</p> <p>2 structure.</p> <p>3 Q. And are you able to tell from this</p> <p>4 image, whether it was curled on placement or curled</p> <p>5 after placement?</p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: No.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. Anything else remarkable about</p> <p>10 Figure Set 10h?</p> <p>11 A. No. Curling, scar encapsulation,</p> <p>12 scar filling.</p> <p>13 Q. Page 59, Figure Set 10i:</p> <p>14 "Neurovascular bundle with rolled TVT tape, S100</p> <p>15 stain. Additional TVT cases."</p> <p>16 Is this from the same or a different</p> <p>17 patient as set 10h?</p> <p>18 A. I don't remember now.</p> <p>19 Q. Do you know if it's a TVT or</p> <p>20 TVT-O?</p> <p>21 A. No.</p> <p>22 Q. What are you trying to show in</p> <p>23 Figure 10h?</p> <p>24 A. It's a single picture for single</p> <p>25 purpose as 10c, on page 52. A neurovascular bundle</p> | <p>1 So I can say that this is abnormal,</p> <p>2 this is a mechanism for symptoms, and then that can</p> <p>3 happen.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. And the reason why you say it's</p> <p>6 abnormal is because the mesh fiber causes this</p> <p>7 bundle to alter its path?</p> <p>8 A. Yes.</p> <p>9 Q. Anything else?</p> <p>10 A. No.</p> <p>11 Q. Page 60.</p> <p>12 A. Yes.</p> <p>13 Q. Figure Set 10j: "A rolled TVT</p> <p>14 sling sectioned parallel and perpendicular to the</p> <p>15 roll. Additional TVT cases."</p> <p>16 Do you know whether this is a TVT or</p> <p>17 TVT-O?</p> <p>18 MR. ORENT: Objection.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. What is the significance of this</p> <p>22 slide to show what you showed in previous slides.</p> <p>23 That is, the fact of the curling?</p> <p>24 A. Fact of the curling and mechanism</p> <p>25 for erosion on page 61, I demonstrate how the</p> |

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| <p>1 erosion occurred. Because one end of this curled 2 tape became eroded. 3 Q. Okay. So this is, the dark end of 4 the tape on page 60 and on 61, it is in fact an 5 erosion? 6 A. Yes, it's -- 7 Q. Where did it erode? 8 A. In the mucosa, in vaginal mucosa. 9 Q. Did it erode into another organ? 10 A. No, it eroded through the mucosa 11 into the vagina. 12 Q. Do you distinguish between an 13 erosion and an exposure? 14 A. Technically, there is a 15 distinction. The terms are used interchangeably, 16 so there is no agreement which one is -- 17 Q. Let's use the technical terms, 18 just so you and are communicating. Is this an 19 erosion or an exposure? 20 A. Both. 21 Q. Okay. 22 A. Because the mucosa eroded on top 23 of it and mesh became exposed. 24 Q. Okay. But in terms of the mesh 25 going into or eroding into another organ, that</p> | <p>1 to see the extent to which this was a painful 2 experience for her? 3 A. This is commonsense. This is a 4 chronic and open wound; would it hurt? Of course 5 it would. 6 Q. Go to page 61. Figure Set 11b. 7 Is this the same mesh? 8 A. No, it's a different one. 9 Q. All right. Is this a TVT or a 10 TVT-O? 11 A. I don't know. 12 Q. And what are you trying to show in 13 Figure Set 11b? 14 A. Similar mechanism for erosion, the 15 mesh somehow rotated, probably through curling of 16 the edges and then became exposed. The edge 17 pierced through the mucosa. 18 Q. And this is an erosion, as you've 19 defined it, in the last section, some people may 20 call it an exposure, correct? 21 A. Yes. It's called -- if you want 22 to call exposure, we will call it exposure. So the 23 mesh became exposed. 24 Q. And what does the mesh in this 25 tissue sample tell you?</p> |
| Page 227 | Page 229 |
| <p>1 didn't happen here? 2 A. Well, it eroded into the mucosa. 3 Q. Okay. But just the mucosa, not 4 the bladder, not the rectum? 5 A. Not the organs. Because it is a 6 different location. 7 Q. All right. And do you remember 8 this patient? 9 A. No. 10 Q. Do you know how this patient was 11 treated? 12 A. By sling excision. 13 Q. Do you know how it worked out? 14 How she recovered from the excision? 15 A. Better that she didn't have eroded 16 mesh anymore after surgery. Maybe it eroded again 17 in a different place. 18 Q. Do you know whether she 19 experienced pain as a part of this? 20 A. Most likely she did. 21 Q. Do you know whether she 22 experienced pain as part of this? 23 A. The degree of pain, as I said, I 24 don't remember now. But most likely she did. 25 Q. You have not consulted her records</p> | <p>1 A. The position, see the position is 2 towards the mucosa. So it's not bilateral to the 3 mucosa, it's angled. And the edge, or the end of 4 the tape became exposed, pierced through the 5 mucosa. And the site of exposure became infected 6 and now there is acute inflammation surrounding. 7 Q. How do you know that this mesh was 8 infected? 9 A. Because there is acute 10 inflammation in there. 11 Q. Do you know how long this woman 12 had this sling before it was removed? 13 A. I don't remember. 14 Q. Are you able to tell from this 15 slide whether this mesh was placed this way or 16 whether it changed after it was placed? 17 A. It's hard to place it like this, 18 because you can see it's clearly perpendicular. So 19 I just cannot imagine it. 20 Q. Do you know? 21 MR. ORENT: Objection. 22 THE WITNESS: I don't know for sure, 23 but this would be a really difficult position to 24 achieve during placement. 25</p> |

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| Page 230 | Page 232 |
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| <p>1 BY MR. THOMAS:</p> <p>2 Q. Anything else remarkable about</p> <p>3 your description of set 11b?</p> <p>4 A. No, we discussed most of it.</p> <p>5 Q. Anything else you want to talk</p> <p>6 about? You said "most".</p> <p>7 A. Sorry.</p> <p>8 Q. Page 63, Figure Set 11c: "Exposed</p> <p>9 edge of TVT sling rotated towards the mucosa.</p> <p>10 Additional TVT cases".</p> <p>11 Do you know whether this is a TVT or</p> <p>12 TVT-O?</p> <p>13 A. No, I don't.</p> <p>14 Q. And what is your purpose of</p> <p>15 including Figure Set 11c?</p> <p>16 A. Just mechanism of exposure,</p> <p>17 because the edge is pointing towards mucosa.</p> <p>18 So it's a near exposed position in this</p> <p>19 case. Probably exposure occurred somewhere either</p> <p>20 more superficial, or deeper in the block.</p> <p>21 Q. As you're looking at that mesh, is</p> <p>22 the mesh -- you show the yellow portion of the mesh</p> <p>23 going from the bottom of the figure to the top of</p> <p>24 the figure. Is that the width of the mesh?</p> <p>25 A. With the length, it's very hard to</p> | <p>1 curls up like this.</p> <p>2 Q. Is this a multiple revision?</p> <p>3 A. I don't know.</p> <p>4 Q. You don't know?</p> <p>5 A. (Witness nods.)</p> <p>6 Q. Okay. For the other mesh</p> <p>7 erosions, or exposures that you've discussed on 58,</p> <p>8 59, 60, 61, 62 and now 63, do you know whether</p> <p>9 those are first revision cases, second revision</p> <p>10 cases, or multiple revision cases?</p> <p>11 MR. ORENT: Objection.</p> <p>12 THE WITNESS: I don't remember exactly.</p> <p>13 Sometimes it's first revision, sometimes five, six</p> <p>14 revisions.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. You just don't know?</p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: If I go through records,</p> <p>19 if it was individual report of a case, I go through</p> <p>20 records thoroughly, so I know exactly how many</p> <p>21 revisions it was.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Go to page 64. Figure Set 11b, is</p> <p>24 that part of Figure Set 11c, or is that different?</p> <p>25 A. No, it's different.</p> |
| Page 231 | Page 233 |
| <p>1 determine in this place. So the mesh is either in</p> <p>2 this shape (indicating), or this shape</p> <p>3 (indicating).</p> <p>4 In any case, one of the edges is</p> <p>5 pointing towards mucosa.</p> <p>6 Q. When you talk about -- strike</p> <p>7 that. This mesh when placed, is going to stretch</p> <p>8 from one side of the abdomen to the other, isn't</p> <p>9 it?</p> <p>10 A. Yes. But we are talking about</p> <p>11 mucosa. So it is a very short stretch of the mesh</p> <p>12 right where it goes between the urethra and vaginal</p> <p>13 wall.</p> <p>14 Q. I understand that. But my point</p> <p>15 is, the only thing that can be exposed there is the</p> <p>16 midpoint, not the ends, correct?</p> <p>17 A. Unless you cut one end, and then</p> <p>18 it becomes exposed again.</p> <p>19 Q. Okay. And in order to cut the</p> <p>20 end, you'd have to cut the end at the vaginal</p> <p>21 mucosa, correct?</p> <p>22 A. Inside. So what happens -- first</p> <p>23 exposure occurs, it curls up like this. So this</p> <p>24 part is exposed, there is a revision surgery, one</p> <p>25 end is cut, the patient is left and sometimes it</p> | <p>1 Q. How can you tell?</p> <p>2 A. It's a different slide.</p> <p>3 Q. Okay. Is it a different patient?</p> <p>4 A. I don't remember.</p> <p>5 Q. Okay.</p> <p>6 A. It may or may not be.</p> <p>7 Q. Okay. Do you know if it's TVT or</p> <p>8 TVT-O?</p> <p>9 A. No.</p> <p>10 Q. Page 65, Figure Set 11e; isn't</p> <p>11 that the same as Figure Set 11c?</p> <p>12 A. I just noticed, something</p> <p>13 happened.</p> <p>14 Q. You liked that one?</p> <p>15 A. Could have been pasted twice or</p> <p>16 selected and pasted -- I don't remember. Something</p> <p>17 happened here. So I probably intended to insert</p> <p>18 different picture, but this one made it.</p> <p>19 Q. Okay. I think we can say that</p> <p>20 63 and 65 came from the same patient?</p> <p>21 A. Yes. It just shows you that I</p> <p>22 don't have an army of people helping me, I'm just</p> <p>23 alone.</p> <p>24 Q. I understand. Let's go to</p> <p>25 page 66, Figure Set 12.</p> |

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| Page 234 | Page 236 |
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| <p>1 A. Yes.</p> <p>2 Q. This is additional TVT cases. Do</p> <p>3 you know whether this is a single mesh or multiple</p> <p>4 meshes?</p> <p>5 A. What do you mean a single mesh --</p> <p>6 Q. There are four frames here.</p> <p>7 Excuse me, there are two frames here.</p> <p>8 Do you know if it's the same one</p> <p>9 patient or two?</p> <p>10 A. No.</p> <p>11 Q. You don't know whether it's one or</p> <p>12 two?</p> <p>13 A. No.</p> <p>14 Q. Do you know whether it's TVT or</p> <p>15 TVT-O?</p> <p>16 A. No.</p> <p>17 Q. What are you trying to show in the</p> <p>18 top image on page 66, Figure Set 12.</p> <p>19 A. Acute inflammation at the site of</p> <p>20 exposure.</p> <p>21 Q. When you say acute inflammation,</p> <p>22 is that different from infection?</p> <p>23 A. No. Acute inflammation is</p> <p>24 reaction to infection. Technically, it's the same</p> <p>25 pathological process.</p> | <p>1 correct?</p> <p>2 A. You're correct.</p> <p>3 Q. Thank you. And in the lower image</p> <p>4 on Figure Set 12, the yellow represents</p> <p>5 polypropylene?</p> <p>6 A. That is correct.</p> <p>7 Q. And the presence of neutrophils</p> <p>8 again shows the acute inflammation?</p> <p>9 A. That's correct.</p> <p>10 Q. Anything else remarkable about</p> <p>11 that slide?</p> <p>12 A. No.</p> <p>13 MR. THOMAS: I need to take a break,</p> <p>14 please.</p> <p>15 -- RECESS AT 3:19 --</p> <p>16 -- UPON RESUMING AT 3:23 --</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Doctor, I understand from prior</p> <p>19 depositions that when you analyzed your</p> <p>20 medical-legal cases that you prepared your own, for</p> <p>21 lack of a better description, your own pathology</p> <p>22 report. I think you called it a synoptic recording</p> <p>23 for each of the plaintiffs?</p> <p>24 A. Not for medical-legal. I do it</p> <p>25 for all mesh cases, it's a part of research.</p> |
| Page 235 | Page 237 |
| <p>1 Q. I was just going to ask you that.</p> <p>2 Can you diagnose infection from this slide?</p> <p>3 A. Yes, I can.</p> <p>4 Q. And based on what?</p> <p>5 A. Based on the acute inflammation.</p> <p>6 Q. Okay. And what is it about the</p> <p>7 slide that shows the acute inflammation?</p> <p>8 A. The neutrophils.</p> <p>9 Q. And the slide below that, again,</p> <p>10 shows acute inflammation, and that may or may not</p> <p>11 be the same patient?</p> <p>12 A. That's correct. I have feeling</p> <p>13 that they are different patients. I think one</p> <p>14 of -- the top one is the later case, the bottom one</p> <p>15 is an earlier case.</p> <p>16 Q. As you sit here, do you know which</p> <p>17 ones they are?</p> <p>18 A. The quality of the histology and</p> <p>19 the quality of the picture.</p> <p>20 Q. In the top image, where you show</p> <p>21 the acute inflammation, is there mesh in that</p> <p>22 image?</p> <p>23 A. Underneath, if you go a little bit</p> <p>24 over.</p> <p>25 Q. This doesn't appear in the image,</p> | <p>1 Q. Do you have those kinds of</p> <p>2 recordings for all of the patients that are in your</p> <p>3 report?</p> <p>4 MR. ORENT: Objection.</p> <p>5 THE WITNESS: May or may not. Probably</p> <p>6 I don't have for all patients. Some cases are</p> <p>7 probably not even signed out, so the report is not</p> <p>8 completed yet.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. I guess my point is that we didn't</p> <p>11 get any of those on your thumb drive. And I'm</p> <p>12 curious if there's some of those that we don't</p> <p>13 have. We have a lot of them in the Huskey, Edwards</p> <p>14 case or the Bellew case -- in the Bellew case, you</p> <p>15 produced those to us for the --</p> <p>16 A. Yes. When I started doing my</p> <p>17 research, I realized that I needed more or less</p> <p>18 standardized approach when I examined the meshes.</p> <p>19 And I started entering them as a</p> <p>20 synoptic report, which is a specific pre-set number</p> <p>21 of parameters, so I don't forget and they're all</p> <p>22 analyzed in the same manner so they can compare</p> <p>23 them. It has nothing to do with medical-legal</p> <p>24 cases, or nothing else. It's pure documentation</p> <p>25 for research purposes.</p> |

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| <p>1 Q. Do you have that for each of the 2 slides that are in this report? 3 A. As I said -- 4 MR. ORENT: Objection. 5 THE WITNESS: -- I don't have all of 6 these patients, some of the reports are not 7 finalized. 8 BY MR. THOMAS: 9 Q. I'm going to ask you to produce 10 those that you do have. 11 I have a -- 12 A. If it's medical-legal case and 13 you're entitled to see the information. 14 Q. Okay. I have a title of a study, 15 we talked before about your chemical oxidation 16 study you were performing, and I asked you about 17 the recipe for the chemicals to which you're 18 exposing the TVTs to. 19 A. You mean hydrogen peroxide with 20 chromium salt catalyst? 21 Q. Yes. 22 A. Okay. I remember. 23 Q. And there was a study we found 24 called, "Controlled Peroxide Degradation of 25 Polypropylene - Rheological Properties and</p> | <p>1 opinions, I would go back in my pool of images, for 2 TVT and TVT-O cases, and search for best images 3 representing that specific feature. 4 Q. I see. So when you say "best 5 images", you went back through about 100 different 6 TVTs and TVT-Os did you say? 7 A. No, I said slings. 8 Q. I'm sorry. How many TVTs and 9 TVT-Os have you looked at? 10 A. Ballpark of 30 to 40. 11 Q. Okay. And so you went back 12 through your 30 to 40 to identify those that best 13 represented the features that you wanted to show? 14 A. Images. 15 MR. ORENT: Objection. 16 BY MR. THOMAS: 17 Q. Okay. Images? 18 A. I didn't take new images of 19 various cases, I just used those images which were 20 taken already. The only new images that I produced 21 are the cases I received as a consulting trial set. 22 (Reporter sought clarification.) 23 A. Trial set, as a set to facilitate 24 at trial. 25 Q. Let's go to Exhibit No. 2.</p> |
| Page 239 | Page 241 |
| <p>1 Prediction of MWD From Rheological Data". Lead 2 author, Azizi, A-Z-I-Z-I. Including I. Ghasemi, 3 G-H-A-S-E-M-I, and M. KARRABI, K-A-R-R-A-B-I; does 4 that ring a bell? 5 MR. ORENT: Objection. 6 THE WITNESS: You're asking the wrong 7 person, I'm really bad with names. I'm a 8 pathologist, I remember the slides but I don't 9 remember the names. 10 BY MR. THOMAS: 11 Q. Do you have the study that you 12 used to come up with the recipe? 13 A. Yes, I do. I can find it in my 14 hard drive, and I can find it. 15 Q. Okay. Good. 16 A. It's most likely at least in the 17 reference materials as well. 18 Q. In the reference materials to your 19 report? 20 A. Yes. 21 Q. Okay. How did you determine which 22 of the slides from your total number of TVT-O and 23 TVT cases to include in the report? 24 A. I went to features. So every time 25 I would be describing a specific feature in the</p> | <p>1 Exhibit No. 2 is your supplemental 2 report served two days ago. 3 A. Yes. 4 Q. And when you received this, you 5 received slides from CAMC? 6 A. Yes. 7 Q. You didn't create your own slides? 8 A. No, I did the staining. 9 (Reporter sought clarification.) 10 A. My lab did staining. 11 Q. Do you know whether this is a TVT 12 or a TVT-O? 13 A. No, I don't remember now. 14 Q. Okay. 15 A. I didn't review any medical 16 records for the consolidated trial cases. 17 Q. And if you look at -- your pages 18 aren't numbered, but the first image, which is 19 identified as supplemental Figure EM1, it says: 20 "Portion of excised mucosa with underlying mesh, 21 H&E magnification equivalent to 1.6X objective". 22 What is the significance of this image? 23 A. It's just from my review showing 24 where the mesh is and how it relates to the mucosa. 25 Q. Is there anything significant</p> |

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| <p style="text-align: right;">Page 242</p> <p>1 about this image in terms of risk factors or issues 2 related to symptoms, clinical symptoms? 3 A. Well, it's close. So it's an 4 overview of the part which didn't get exposed but 5 it shows the proximity. You know, that's 6 significant. 7 Q. And again, you don't know whether 8 that was placed there or if it migrated there after 9 placement, correct? 10 MR. ORENT: Objection. 11 THE WITNESS: That's correct. 12 BY MR. THOMAS: 13 Q. Okay. Anything else remarkable 14 about supplemental Figure EM1? 15 A. No, there's scar tissue which 16 encapsulates and fills the pore; that's about it. 17 Q. Okay. Supplemental Figure EM2. 18 Is this part of the same slide or is this a 19 different slide? 20 A. Oh, it's the same block. 21 Q. Got it. 22 A. Yeah, I think it's the same slide 23 because I had only one H&E slide. 24 Q. It says in the first page you 25 received unstained histological slides, plural.</p> | <p style="text-align: right;">Page 244</p> <p>1 showing supplemental Figure EM3? 2 A. Again, shows mucosa and proximity 3 of the mesh to mucosa. There is less than a half 4 millimeter between the mesh and mucosa. 5 Q. What is the distance between those 6 two mesh fibers that are shown there? 7 A. About a millimeter. 8 Q. Okay. Supplemental Figure EM4, 9 again, you're showing the foreign body inflammatory 10 reaction? 11 A. That's correct. 12 Q. If you go to supplemental Figure 13 EM5? 14 A. Yes. 15 Q. You indicate in the description, 16 "acute inflammation and indication of mesh erosion 17 and bacterial infection". 18 Do you know whether this patient was 19 diagnosed with an infection? 20 A. No, I didn't read the records. I 21 can see clearly there is bacterial infection 22 triggering acute inflammation. If they saw it 23 clinically or they didn't, I don't know. But even 24 if they didn't, I would tell them there was an 25 infection.</p> |
| <p style="text-align: right;">Page 243</p> <p>1 Did you only have one? 2 A. For H&E, I stain only one slide. 3 So one slide was stained by H&E method, one slide 4 smooth muscle actin, and one slide S100 protein. 5 Q. Okay. So supplemental Figure EM2 6 is just more of a magnification of Figure EM1, 7 correct? 8 A. Yes, I think you can match it, 9 it's from here. 10 Q. And again, what you're trying to 11 show is the foreign body reaction and inflammation? 12 A. That is correct. 13 Q. Where is the bark in this image? 14 A. Which image? The EM2? 15 Q. Yes. 16 A. Maybe out of focus, maybe not 17 there. 18 Q. Okay. If you go to supplemental 19 Figure EM3, this is another portion of the same 20 image, correct? 21 A. I think it's a different fragment, 22 from the same slide but from a different piece of 23 tissue. There were several pieces of tissue on the 24 slide. 25 Q. I see. And what is the purpose of</p> | <p style="text-align: right;">Page 245</p> <p>1 Q. Okay. Are you able to tell from 2 these images that there was in fact a mesh erosion 3 or mesh exposure? 4 A. Yes. 5 Q. And how can you tell that? 6 A. There was a breakdown of mucosa 7 and entry for infection. That's why I can see 8 acute inflammation. 9 Q. Where is the breakdown of the 10 mucosa? 11 A. I don't know. It didn't get in 12 the section. 13 Q. Are you assuming there's a 14 breakdown of mucosa? You don't show one on the 15 slide, correct? 16 A. It's not an assumption. I can 17 tell you with 100 percent certainty that there was 18 a breakdown in the mucosa. Because if mucosa is 19 not broken down, there is no bacterial insemination 20 and acute inflammation. 21 Q. Supplemental Figure EM6, you 22 identify an obliterated artery? 23 A. That is correct. 24 Q. Anything remarkable about that 25 finding beyond what we've talked about before, the</p> |

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| <p style="text-align: right;">Page 246</p> <p>1 other obliterated artery?</p> <p>2 A. No. Exactly the same finding;</p> <p>3 interrupted blood supply.</p> <p>4 Q. Which may or may not have clinical</p> <p>5 significance?</p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: The degree of the changes</p> <p>8 may or may not be clinically apparent.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Okay. Because if the blood flow</p> <p>11 is reduced or interrupted, they may receive blood</p> <p>12 flow from other sources that would vascularize this</p> <p>13 area?</p> <p>14 A. Yes. And then that was fibrosis,</p> <p>15 and then you mix up fibrosis which is caused by the</p> <p>16 mesh, then fibrosis lead to ischemia.</p> <p>17 It's a complex setting; how much of</p> <p>18 that would translate from one specific symptom</p> <p>19 would be difficult to discern.</p> <p>20 Q. Obliteration of arteries is a risk</p> <p>21 in any surgery of the pelvic floor, isn't it?</p> <p>22 MR. ORENT: Objection.</p> <p>23 THE WITNESS: Yes, there would be a</p> <p>24 risk for obliterated artery. But when you say</p> <p>25 obliterated artery in the tissue, which is not</p> | <p style="text-align: right;">Page 248</p> <p>1 on the upper right-hand corner, how far is that</p> <p>2 from the mesh?</p> <p>3 A. This one is --</p> <p>4 Q. I'm talking about this one, upper</p> <p>5 right?</p> <p>6 A. Oh, this one. See, with this one</p> <p>7 I don't even know. Maybe there is fiber right</p> <p>8 there, so it's pinching it.</p> <p>9 Q. Do you know whether that's fiber</p> <p>10 or not?</p> <p>11 A. That is hard to determine, I</p> <p>12 suspect there is, but I wasn't sure therefore I</p> <p>13 didn't put it.</p> <p>14 Now, looking at this image, I think</p> <p>15 there was a fiber. So that curvilinear shape is</p> <p>16 actually fiber compressing.</p> <p>17 Q. How do you know that without</p> <p>18 looking at it?</p> <p>19 A. Well, there's density, increased</p> <p>20 density. Similar to this area, the collagen is</p> <p>21 compacted right around the fibers.</p> <p>22 Q. The tissue itself is pretty</p> <p>23 irregular, isn't it?</p> <p>24 A. Well, see, this is clearly not the</p> <p>25 place where mesh fiber was. Because there is no</p> |
| <p style="text-align: right;">Page 247</p> <p>1 changed otherwise, because to obliterate an artery</p> <p>2 during surgery, you have to transect it.</p> <p>3 So by the time of mesh placement, this</p> <p>4 part would be separated. So this is an intact</p> <p>5 structure, which was not transected during surgery.</p> <p>6 It became obliterated later on.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. If you go to supplemental -- how</p> <p>9 can you tell that it happened after placement?</p> <p>10 A. It's not transected during</p> <p>11 surgery.</p> <p>12 Q. I see.</p> <p>13 A. See how are the arteries being</p> <p>14 damaged --</p> <p>15 Q. I understand.</p> <p>16 A. -- they get transected.</p> <p>17 Q. I understand. Supplemental Figure</p> <p>18 EM7a, "innervation of the scar tissue encapsulating</p> <p>19 the mesh, S100". What are you showing in EM7a?</p> <p>20 A. Nerve branch. EM7a and 7b is the</p> <p>21 same image; 7b is labeled copy of 7a.</p> <p>22 Q. Okay. And the arrows are pointing</p> <p>23 to what?</p> <p>24 A. Nerve branches, or nerves.</p> <p>25 Q. And for the nerve and nerve branch</p> | <p style="text-align: right;">Page 249</p> <p>1 capsule. If you look here, there is a capsule</p> <p>2 around the fiber, and if you look there, there is a</p> <p>3 capsule around the fiber. So I suspect there was a</p> <p>4 fiber here.</p> <p>5 Q. Okay.</p> <p>6 A. Not here, but there.</p> <p>7 Q. Looking at those nerves, is there</p> <p>8 anything about the appearance of those nerves on</p> <p>9 light microscopy that suggests to you they were</p> <p>10 causing pain to the patient while the mesh was in</p> <p>11 place?</p> <p>12 A. Could you repeat the question.</p> <p>13 I'm getting tired, sorry.</p> <p>14 MR. THOMAS: Would you repeat it for</p> <p>15 me, please?</p> <p>16 -- REPORTER'S NOTE: Question read back</p> <p>17 as recorded above.</p> <p>18 THE WITNESS: They're healthy nerves</p> <p>19 which can conduct pain. This is one of the main</p> <p>20 findings.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Okay. But again, there's nothing</p> <p>23 about those that allow you to state that those</p> <p>24 nerves were in fact reacting in a way to cause pain</p> <p>25 in a patient while the mesh was implanted?</p> |

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| <p style="text-align: right;">Page 250</p> <p>1 A. The point of the picture is to</p> <p>2 show that that tissue is sensitive, so it can sense</p> <p>3 pain.</p> <p>4 Those nerve branches are not directly</p> <p>5 affected or at least one may, but the others are</p> <p>6 not directly affected by the mesh.</p> <p>7 The point is that tissue around it is</p> <p>8 innervated, so if you get a formation, if you get</p> <p>9 distortion, mechanical compression, then it can</p> <p>10 sense pain.</p> <p>11 Q. Okay. Page 67 of your first</p> <p>12 report, Figure Set 13a, you're talking about the</p> <p>13 Prolene degradation layer.</p> <p>14 Do you know if this is TVT or TVT-O?</p> <p>15 A. No.</p> <p>16 Q. Do you know from what case this</p> <p>17 comes?</p> <p>18 MR. ORENT: Objection.</p> <p>19 THE WITNESS: One of the consolidated</p> <p>20 cases.</p> <p>21 It's so similar to this study, which I</p> <p>22 think our scientists did in 87. I mean, even the</p> <p>23 arrow there is so similar.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. So all of these images are from</p> | <p style="text-align: right;">Page 252</p> <p>1 A. Not image, slide.</p> <p>2 Q. Slide, I'm sorry. Thank you.</p> <p>3 A. It came detached and displaced.</p> <p>4 Q. Okay. And left what you have</p> <p>5 described as the bark behind?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. All right. Now, if you go to the</p> <p>8 next page, page 73, again, additional TVT cases you</p> <p>9 show an image where you show the polypropylene</p> <p>10 still in place, correct?</p> <p>11 A. Yes. So now there is a</p> <p>12 separation. The core separated from the bark, but</p> <p>13 the core didn't detach completely and floated away.</p> <p>14 It's still close, but there was a split.</p> <p>15 Q. And this is detached as a part of</p> <p>16 the sample preparation process, correct?</p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: I don't know when it</p> <p>19 became detached. During surgery or during</p> <p>20 sectioning or during processing of the specimen.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Didn't happen in vivo, didn't</p> <p>23 happen in the body?</p> <p>24 A. No. I suspect it doesn't happen</p> <p>25 that often. I very rarely see the bark actually in</p> |
| <p style="text-align: right;">Page 251</p> <p>1 the consolidated cases through 72, and our experts</p> <p>2 have these images, correct?</p> <p>3 A. Images -- they have slides.</p> <p>4 Q. Slides, that's what I meant.</p> <p>5 A. Yes.</p> <p>6 Q. I've talked to you, you've been</p> <p>7 talked to at length about these images in prior</p> <p>8 cases. Is there anything new and different about</p> <p>9 what's expressed in these images that you haven't</p> <p>10 seen before?</p> <p>11 A. It is exactly what I described in</p> <p>12 the published papers and previous reports. Exactly</p> <p>13 all, everything is the same.</p> <p>14 Q. For the other cases that you begin</p> <p>15 on 73, you had images from additional TVT cases.</p> <p>16 Do you know whether those are TVT or TVT-O?</p> <p>17 A. No.</p> <p>18 MR. ORENT: Objection.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. If you go to page 72, please?</p> <p>21 A. Yes.</p> <p>22 Q. On page 72, you show an empty</p> <p>23 space of detached core on the right image. And a</p> <p>24 separated degradation bark. The empty space means</p> <p>25 that the polypropylene dropped out of the image?</p> | <p style="text-align: right;">Page 253</p> <p>1 the tissue, being displaced in the tissue away from</p> <p>2 the fibers.</p> <p>3 Q. Have you studied how mechanically</p> <p>4 that happens?</p> <p>5 A. It just breaks off. There is a</p> <p>6 shear force, a breaking force.</p> <p>7 Q. When you say a shear force, does</p> <p>8 it shear off at the point where -- at about five</p> <p>9 microns as the degradation ceases?</p> <p>10 A. It shears off in the interface</p> <p>11 between degraded and non-degraded.</p> <p>12 Q. That's my point. Let's see if we</p> <p>13 can agree with this. We're dealing with visual</p> <p>14 observations here, correct?</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. And is it fair to understand with</p> <p>17 respect to the images on page 73, where you show</p> <p>18 detached core and degradation bark separated, are</p> <p>19 you telling me that the detached core no longer has</p> <p>20 a bark on it?</p> <p>21 A. They have a really thin layer of</p> <p>22 degraded material. Because the bark itself is not</p> <p>23 uniform. There is a higher degree of degradation</p> <p>24 on the outside and then smaller, smaller, smaller,</p> <p>25 smaller, smaller.</p> |

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| <p>1 Q. Right.</p> <p>2 A. And then the degradation blends</p> <p>3 into not degraded polypropylene.</p> <p>4 Q. Right.</p> <p>5 A. So at certain point these micro</p> <p>6 cracks, and mono cracks, they cannot go into this</p> <p>7 completely solid material, so it shears off</p> <p>8 somewhere there.</p> <p>9 I don't know if it's right at the end</p> <p>10 of them, close to them or how far they are. So</p> <p>11 there might be a layer of degraded polypropylene on</p> <p>12 the core. How thick it is, I wouldn't know.</p> <p>13 Q. It's too small to measure by your</p> <p>14 technique?</p> <p>15 A. That's correct.</p> <p>16 Q. And your best estimate is that the</p> <p>17 degradation bark that appears, as you've described</p> <p>18 it in 73, is much as five microns?</p> <p>19 A. This is thinner. By looking at</p> <p>20 it, it is around two microns.</p> <p>21 Q. Now what you show on page 75,</p> <p>22 again from additional TVT cases, are the cracks</p> <p>23 which you believe to be oxidized polypropylene,</p> <p>24 correct?</p> <p>25 A. I don't believe -- I know.</p> | <p>1 A. And I figure I just leave it long</p> <p>2 enough, soon enough it will form and I will see</p> <p>3 which would -- in which fluid the bark is thicker.</p> <p>4 Q. We talked before, I believe at</p> <p>5 trial, about xylene and that you were conducting a</p> <p>6 test to determine the extent to which xylene</p> <p>7 impacted Prolene polypropylene; do you remember</p> <p>8 that?</p> <p>9 A. Yes, I do.</p> <p>10 Q. You told me, I believe, that you</p> <p>11 were currently testing xylene to determine whether</p> <p>12 xylene would impact Prolene polypropylene. Are you</p> <p>13 still conducting that test?</p> <p>14 A. It's in the same set of jars. One</p> <p>15 of the jars contains xylene.</p> <p>16 Q. Is that the only test that you're</p> <p>17 doing with xylene?</p> <p>18 A. Well, previously I did testing for</p> <p>19 processing. So new mesh was put in regular xylene</p> <p>20 solution for time when it happens during tissue</p> <p>21 process.</p> <p>22 Q. Did you produce that to me in the</p> <p>23 jump drive Exhibit 4.</p> <p>24 A. No, these are the images of new</p> <p>25 pristine mesh. So this mesh had been through</p> |
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| <p>1 Q. Okay. And Figure Set 13i, do you</p> <p>2 know if this is a TVT or TVT-O?</p> <p>3 A. No.</p> <p>4 Q. Do you know how long this was in</p> <p>5 the body?</p> <p>6 A. Certainly more than a year.</p> <p>7 Q. Why do you say that?</p> <p>8 A. It's relatively thick. So if I</p> <p>9 check here where it's less tangential, this is the</p> <p>10 thickness, so it's definitely more than a year.</p> <p>11 Q. When you devised your experiment</p> <p>12 to intentionally oxidize polypropylene, did you</p> <p>13 look at any methods that would allow you to</p> <p>14 intentionally oxidize polypropylene in a time of</p> <p>15 less than a year and a half?</p> <p>16 A. No, I didn't take them out.</p> <p>17 Q. You misunderstood my question.</p> <p>18 Did you attempt to identify any kind of</p> <p>19 chemical recipe that would allow you to</p> <p>20 intentionally oxidize Prolene more quickly than a</p> <p>21 year and a half?</p> <p>22 A. No.</p> <p>23 Q. Why not?</p> <p>24 A. I'm busy enough with other things.</p> <p>25 Q. Okay.</p> | <p>1 xylene.</p> <p>2 Q. Okay. Did you do any other</p> <p>3 testing of pristine mesh impact on xylene over a</p> <p>4 period of time?</p> <p>5 A. No. These only two. I did</p> <p>6 experiment for our routine processing, routine</p> <p>7 exposure to xylene, and then I started this</p> <p>8 experiment.</p> <p>9 I was testing it within month or two</p> <p>10 after it became exposed. I was thinking maybe it</p> <p>11 would get dissolved; it didn't. But the long-term</p> <p>12 effect will be studied later on together with other</p> <p>13 solutions.</p> <p>14 Q. When you put the pristine mesh</p> <p>15 through the sample preparation process, did you</p> <p>16 perform any analytical chemistry on the mesh to</p> <p>17 determine the extent to which xylene may have</p> <p>18 altered the chemical structure of polypropylene?</p> <p>19 A. No.</p> <p>20 Q. On page 84?</p> <p>21 A. Yes.</p> <p>22 Q. Is page 84 another image of what</p> <p>23 we had talked about at length on page 83?</p> <p>24 A. No, this is a different case.</p> <p>25 This is a case consolidated case. This is</p> |

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| <p>1 appearance of case from -- you can see the name of 2 the patient.</p> <p>3 Q. Okay. So this is -- strike that. 4 Did you do any analysis for bark on the 5 mesh depicted in Figure 16a?</p> <p>6 A. It's embedded in histology. It's 7 there. I mean --</p> <p>8 Q. Have you ever done it? 9 A. I didn't do anything specific. 10 It's embedded in histology. I can pull the slide 11 and take picture of the bark.</p> <p>12 But again, this is a St. Michael's 13 patients, I'm not comfortable disclosing or giving 14 pictures specifically for trial or anything else. 15 I can tell you that I saw the bark.</p> <p>16 Q. So, Figure 16b on page 84 is 17 cracking on the surface of TVT mesh fibers. And 18 this is from the consolidated cases for patient 19 Dameron; is that correct?</p> <p>20 A. That is correct.</p> <p>21 Q. And these are the tissue samples 22 that you show on 84 that you had available to you?</p> <p>23 A. Yes.</p> <p>24 Q. And they had been stored in 25 formalin?</p> | <p>1 Q. -- entitled, "Safety 2 Considerations for Synthetic Sling Surgery". 3 I know Dr. Blaivas. Who is Dr. 4 Purohit?</p> <p>5 A. I don't know. It's a team of 6 urologists and fellows working with Dr. Blaivas.</p> <p>7 Q. Okay. Did you consult with Dr. 8 Blaivas on the content of this article?</p> <p>9 A. Well, we wrote it together.</p> <p>10 Q. And that's my point. Did you work 11 with this whole team in writing the article?</p> <p>12 A. Yeah. We were changing, everybody 13 was contributing. It was changed several times, 14 redacted and...</p> <p>15 Q. Did you work with any individual 16 specifically, or did you write your own piece and 17 just look after your own section of the article?</p> <p>18 A. Oh, it's a joint effort. I mean, 19 the manuscript consult, everybody contributes, puts 20 one piece there, puts one piece there.</p> <p>21 It's been changed and then editorial 22 office changes and then we change back and then so 23 forth. By the end of the day each single word may 24 be coming from a different person.</p> <p>25 Q. How many drafts did this Exhibit 5</p> |
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| <p>1 A. No. We received it dry. Your 2 expert was there.</p> <p>3 Q. Okay. 4 A. It was jar without formalin.</p> <p>5 Q. Do you know whether it was in 6 formalin?</p> <p>7 A. I don't. Probably it was at one 8 time, it leaked out but... that's my assumption.</p> <p>9 Q. You do know how long this was in 10 the body?</p> <p>11 A. No.</p> <p>12 Q. And obviously you don't know how 13 it was handled before it got to you, correct?</p> <p>14 A. No.</p> <p>15 EXHIBIT NO. 5: Study Entitled "Safety 16 Considerations for Synthetic Sling 17 Surgery" in which Dr. Vladimir Iakovlev 18 appears as an author.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Doctor, I'm going to hand you 21 what's been marked as deposition Exhibit No. 5.</p> <p>22 A. Yes.</p> <p>23 Q. Deposition Exhibit No. 5 is a 24 review study in which you appear as an author -- 25 A. Yes.</p> | <p>1 go through? 2 A. Five, six.</p> <p>3 Q. Do you still have those drafts? 4 MR. ORENT: Objection.</p> <p>5 THE WITNESS: Yes, I do. But I mean 6 this is more of a delicate issue because there are 7 many authors involved and there is research 8 produced information, and it's a work in progress.</p> <p>9 What became public is what we see right 10 in front of us. What we decided to be correct to 11 be exposed to the public.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Other than the journal itself, was 14 anybody else involved in the preparation of 15 Exhibit 5?</p> <p>16 A. What do you mean?</p> <p>17 Q. Did you have any contribution from 18 any other source other than the authors that were 19 listed in the preparation of the article?</p> <p>20 A. Everybody listed as authors, 21 everybody who contributed is here. Well, editorial 22 office was working with it also.</p> <p>23 Q. And who did you work with at the 24 editorial office?</p> <p>25 A. I don't remember now.</p> |

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| <p>1 Q. Okay.</p> <p>2 A. I mean, they send their paper,</p> <p>3 they said, okay, this revision needs to be</p> <p>4 reviewed, please check this, please check that,</p> <p>5 they suggest some changes, mainly just style. Very</p> <p>6 strict regarding style.</p> <p>7 Q. You said something earlier today,</p> <p>8 I want to make sure I understand. In this</p> <p>9 document, there is reference to work that you have</p> <p>10 done on different meshes in the medical-legal</p> <p>11 setting.</p> <p>12 I thought I understood you to say that</p> <p>13 you didn't use the slides that were provided to you</p> <p>14 by Dr. Kreutzer, but that you cut new slides from</p> <p>15 existing blocks and conducted your analysis on</p> <p>16 those new slides; is that correct?</p> <p>17 A. For some cases, I received only</p> <p>18 slides, stained and unstained. For some cases I</p> <p>19 received blocks. As far as I remember, it's been</p> <p>20 long time.</p> <p>21 So I could either use unstained slides</p> <p>22 which came together with stained slides, or I could</p> <p>23 ask my lab to do recuts from the blocks which were</p> <p>24 made before me.</p> <p>25 Q. All right. So, your best</p> | <p>1 reporting longer-term complications, reports pain</p> <p>2 greater than six weeks for either retropubic or</p> <p>3 transobturator tape slings at 3.5 percent, correct?</p> <p>4 A. Which line?</p> <p>5 Q. Third from the bottom, longer-term</p> <p>6 complications. Do you see it, for refractory pain</p> <p>7 greater than six weeks?</p> <p>8 A. So the incidence range is from 4.1</p> <p>9 to 30 percent.</p> <p>10 Q. The complications percentage of</p> <p>11 patients that report refractory pain greater than</p> <p>12 six weeks is 3.5 percent, correct?</p> <p>13 A. What I see is 4.1 to 30 percent.</p> <p>14 Q. Well --</p> <p>15 A. Third line from the bottom.</p> <p>16 Q. I understand that's the mean and</p> <p>17 the range, correct?</p> <p>18 A. Yes.</p> <p>19 Q. 4.1?</p> <p>20 A. Sorry, 4.1 is mean. Yes, you're</p> <p>21 correct. I need my glasses.</p> <p>22 So this is -- the range is from 0 to</p> <p>23 30 percent.</p> <p>24 Q. But the average -- excuse me --</p> <p>25 the percentage of patients at 7,084 that report</p> |
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| <p>1 recollection it was a mixture of previously</p> <p>2 existing slides or recuts from this mesh that you</p> <p>3 had obtained from Dr. Kreutzer, correct?</p> <p>4 A. Yes.</p> <p>5 Q. Is the same thing true with your</p> <p>6 other mesh specimens that were involved in</p> <p>7 medical-legal field, that on some occasions you'd</p> <p>8 use existing slides and some occasions you'd use</p> <p>9 recuts or you'd have recuts made of existing</p> <p>10 blocks?</p> <p>11 A. That's correct. Depends on</p> <p>12 situation.</p> <p>13 Q. I assume you stand by all the</p> <p>14 findings in this report, correct?</p> <p>15 A. It's not findings; this report is</p> <p>16 a review. So it's more based on the other papers.</p> <p>17 Q. Okay?</p> <p>18 A. The only thing which was produced</p> <p>19 in this paper from us personally was figures.</p> <p>20 Q. Let's go to one of those figures</p> <p>21 on page 4.</p> <p>22 A. You mean the table?</p> <p>23 Q. Table two on page 4?</p> <p>24 A. Yes.</p> <p>25 Q. And this review paper, in</p> | <p>1 pain greater than six weeks, is 247 or 3.5 percent,</p> <p>2 correct? Is that right?</p> <p>3 A. Yes and no. So this is a review</p> <p>4 of previously published studies. So the quality of</p> <p>5 the studies is different, methodology is different.</p> <p>6 But when you check them, the pain over six weeks is</p> <p>7 reporting anywhere from 0 to 30 percent.</p> <p>8 Q. Okay.</p> <p>9 A. With a mean, or average</p> <p>10 4.1 percent.</p> <p>11 Q. But these numbers are correct,</p> <p>12 aren't they?</p> <p>13 A. Well, from what we extracted at</p> <p>14 that stage from the papers, that's what we have.</p> <p>15 Q. Okay. You went out and tried to</p> <p>16 obtain complication rates for retropubic or TOT</p> <p>17 slings, didn't you?</p> <p>18 A. Yes. The whole paper is just for</p> <p>19 slings.</p> <p>20 Q. And as a part of looking at</p> <p>21 long-term pain which is greater than six weeks, you</p> <p>22 looked at 7,084 patients, correct?</p> <p>23 A. No, we didn't. The papers in</p> <p>24 combination.</p> <p>25 Q. I understand. But you gathered</p> |

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| <p>1 papers that looked at over 7,000 patients?</p> <p>2 MR. ORENT: Objection.</p> <p>3 THE WITNESS: That's what it says</p> <p>4 there, yes.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. And in gathering the papers, who</p> <p>7 was in charge of picking which studies you looked</p> <p>8 at?</p> <p>9 A. That part -- it's not a study; it</p> <p>10 is a review.</p> <p>11 Q. I apologize.</p> <p>12 A. That part of the review was done</p> <p>13 mainly by urologist.</p> <p>14 Q. Do you know who that was?</p> <p>15 A. It's a team working with Dr.</p> <p>16 Blaivas.</p> <p>17 Q. So the urologist, the clinicians,</p> <p>18 are the people who are responsible for identifying</p> <p>19 the studies to identify the complication rates?</p> <p>20 A. That's correct.</p> <p>21 Q. And through their best efforts,</p> <p>22 they identified a percentage of patients that have</p> <p>23 pain more than six weeks at 3.5 percent, correct?</p> <p>24 A. That was an estimate of a minimal,</p> <p>25 a minimum number. So this is the bottom line. So</p> | <p>1 complications looked to see how many people had</p> <p>2 their pain resolved by surgery or some other</p> <p>3 treatment?</p> <p>4 A. Those papers are reviews. Most of</p> <p>5 them didn't provide that information. They just</p> <p>6 provided numbers for complications.</p> <p>7 Q. Did you do a literature search</p> <p>8 yourself to determine the extent to which long-term</p> <p>9 complications of chronic pain were resolved by</p> <p>10 surgery or other treatment?</p> <p>11 A. Not to answer that specific</p> <p>12 question. Again, I mean, I only can read what is</p> <p>13 published. Because studies don't concentrate,</p> <p>14 don't focus on this question; I cannot get an</p> <p>15 answer.</p> <p>16 Q. Well, this was your group's best</p> <p>17 effort at presenting, in a reviewed paper, the rate</p> <p>18 of complications for long-term pain, correct?</p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: Yes, you're correct.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Thank you.</p> <p>23 A. But the question is that if I made</p> <p>24 an effort to look for something which is barely</p> <p>25 ever published; that's why I answered that it's</p> |
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| <p>1 it's minimum of 3.5 percent of the patients will</p> <p>2 develop chronic pain.</p> <p>3 Q. Okay.</p> <p>4 A. Which is -- probably doesn't say</p> <p>5 right away, but that was the minimum. It wasn't</p> <p>6 that we were implying that it's a true number.</p> <p>7 Q. Do you know how many, for how many</p> <p>8 of those 3.5 percent that the pain was ultimately</p> <p>9 resolved?</p> <p>10 A. Again, 3.5 percent was minimum</p> <p>11 number.</p> <p>12 Q. I understand. But for some of</p> <p>13 those people they were cured of the chronic pain,</p> <p>14 weren't they?</p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: After mesh removal?</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Or for whatever treatment?</p> <p>19 MR. ORENT: Objection.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Do you know that?</p> <p>22 A. No, I don't know. I don't think</p> <p>23 it was in the published literature.</p> <p>24 Q. That's fine. Do you know whether</p> <p>25 the urologist group who were looking at the mesh</p> | <p>1 specifically to that question, would be difficult</p> <p>2 to do.</p> <p>3 -- RECESS AT 4:08 --</p> <p>4 -- UPON RESUMING AT 4:15 --</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Doctor, let's go back to Exhibit</p> <p>7 No. 5, page 5. I asked you about the wrong chart.</p> <p>8 I asked you about the chart on page 4.</p> <p>9 The chart on page 4 does retropubic and</p> <p>10 obturator slings. The one on page 5 is limited to</p> <p>11 retropubic slings; do you see at the top?</p> <p>12 A. Yes.</p> <p>13 Q. And retropubic slings are what TVT</p> <p>14 slings are, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And the long-term refractory pain</p> <p>17 greater than six weeks reported by your group is</p> <p>18 1.8 percent, correct?</p> <p>19 A. Yes, but it's not reported by our</p> <p>20 group.</p> <p>21 Q. Collected by your group?</p> <p>22 A. Collected from other papers by our</p> <p>23 group, yes.</p> <p>24 Q. And as a part of that, the group</p> <p>25 looked at studies reporting on about 2,328</p> |

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| <p>1 patients, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. For the slide on page 82,</p> <p>4 about the -- 83, I'm sorry. About the image of the</p> <p>5 TVT mesh fibers immediately after surgery removal?</p> <p>6 A. Yes.</p> <p>7 Q. Did you submit any histology to</p> <p>8 the journal for publication?</p> <p>9 A. For this case?</p> <p>10 Q. For the journal. For --</p> <p>11 A. Which one?</p> <p>12 Q. In one of the studies you have the</p> <p>13 image of that --</p> <p>14 A. It's --</p> <p>15 Q. Is it the other journal?</p> <p>16 A. Yes, this one.</p> <p>17 Q. I'll come back to that.</p> <p>18 A. You mean histology of that</p> <p>19 specific case?</p> <p>20 Q. Yes.</p> <p>21 A. No.</p> <p>22 Q. Have you shared the histology of</p> <p>23 that specific slide with anybody period?</p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: No.</p> | <p>1 and Dr. Bendavid on this?</p> <p>2 A. Yes.</p> <p>3 Q. Did you receive any funding for</p> <p>4 your work in Exhibit 6?</p> <p>5 A. No.</p> <p>6 Q. Did Dr. Guelcher or Dr. Bendavid</p> <p>7 receive any funding for their work on Exhibit 6?</p> <p>8 A. No. The work actually was done</p> <p>9 mainly by me. Dr. Guelcher and Dr. Bendavid just</p> <p>10 contributed to the drafting of the manuscript.</p> <p>11 Q. What did Dr. Guelcher contribute</p> <p>12 to the manuscript?</p> <p>13 A. The drafting of the manuscript, we</p> <p>14 discussed mechanism of degradation, mechanically</p> <p>15 how it happens, oxidation and other aspects.</p> <p>16 Q. Do you view Dr. Guelcher as</p> <p>17 authoritative on the issue of oxidative</p> <p>18 degeneration -- excuse me.</p> <p>19 Do you view Dr. Guelcher as</p> <p>20 authoritative in the area of oxidative degradation</p> <p>21 of polypropylene?</p> <p>22 A. He's a bio engineer. He works in</p> <p>23 the area.</p> <p>24 Q. How do you feel about him? Do you</p> <p>25 view him as authoritative in the field?</p> |
| Page 271 | Page 273 |
| <p>1 BY MR. THOMAS:</p> <p>2 Q. So you're the only one that's ever</p> <p>3 looked at it?</p> <p>4 A. Pardon?</p> <p>5 Q. You're the only one that's ever</p> <p>6 looked at it?</p> <p>7 A. Yes. I don't think I have</p> <p>8 pictures, I didn't take pictures.</p> <p>9 Q. Okay. Why not?</p> <p>10 A. What for?</p> <p>11 Q. Okay.</p> <p>12 EXHIBIT NO. 6: Article entitled,</p> <p>13 "Degradation of Polypropylene in Vivo:</p> <p>14 A Microscopic Analysis of Mesh</p> <p>15 Explanted from Patients."</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Let me show you what's been marked</p> <p>18 as deposition Exhibit No. 6.</p> <p>19 Deposition Exhibit No. 6 is an article</p> <p>20 entitled, "Degradation of Polypropylene in Vivo: A</p> <p>21 Microscopic Analysis of Mesh Explanted from</p> <p>22 Patients". That was just recently released,</p> <p>23 correct?</p> <p>24 A. That is correct.</p> <p>25 Q. And you worked with Dr. Guelcher</p> | <p>1 MR. ORENT: Objection.</p> <p>2 THE WITNESS: I'm not sure if I can</p> <p>3 answer that question.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Okay?</p> <p>6 A. He's a specialist who works in the</p> <p>7 area and works in the field.</p> <p>8 Q. At any time, have you relied upon</p> <p>9 Dr. Guelcher to tell you, chemically, how</p> <p>10 polypropylene oxidizes?</p> <p>11 A. No. In fact, it wasn't my purpose</p> <p>12 to answer the question how it oxidizes. It only</p> <p>13 describes that it does oxidize.</p> <p>14 Q. So what role did Dr. Guelcher play</p> <p>15 in the preparation of Exhibit 6?</p> <p>16 A. Drafting of the manuscript, mainly</p> <p>17 the discussion part. He also suggested at one</p> <p>18 point when we started working on this, doing a</p> <p>19 myeloperoxidase stain. Again, in relation to</p> <p>20 oxidative degradation.</p> <p>21 Q. What role did Dr. Bendavid have in</p> <p>22 this study?</p> <p>23 A. Well, he actually brought me to</p> <p>24 this mesh field and he supplied, or some samples</p> <p>25 came from Shouldice Hospital, where he worked. And</p> |

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| <p>1 he also helped drafting the manuscript.</p> <p>2 Q. In terms of the data gathering and</p> <p>3 the conclusions contained herein, is this basically</p> <p>4 your work?</p> <p>5 A. For the most part.</p> <p>6 Q. And I hate to ask you again, but</p> <p>7 what data gathering or conclusions did Dr. Guelcher</p> <p>8 or Dr. Bendavid provide?</p> <p>9 A. Dr. Guelcher didn't gather any</p> <p>10 data. As you can read the manuscript or paper,</p> <p>11 it's all histology.</p> <p>12 Q. Okay?</p> <p>13 A. So I've been collecting data and</p> <p>14 analyzing the samples.</p> <p>15 But Dr. Bendavid contributed with idea</p> <p>16 of degradation and contributing some samples,</p> <p>17 hernia samples, and Dr. Guelcher contributed in</p> <p>18 drafting the manuscript and also suggesting</p> <p>19 myeloperoxidase stain and suggesting what is the</p> <p>20 mechanism of degradation.</p> <p>21 But the histology itself, data</p> <p>22 collection and analysis, was done by me.</p> <p>23 Q. As part of the preparation of this</p> <p>24 paper, did you and your coauthors discuss</p> <p>25 intentionally oxidizing polypropylene to see if it</p> | <p>1 what he's using, or I don't remember exactly how</p> <p>2 the conversation started, and he said that he's</p> <p>3 using recipe from that specific paper.</p> <p>4 Q. I see.</p> <p>5 A. And I used it. We didn't have</p> <p>6 exchange of the samples, or testing of each other's</p> <p>7 samples.</p> <p>8 Q. So you have never analyzed the</p> <p>9 samples that he tested?</p> <p>10 A. No, never seen those.</p> <p>11 Q. And you know that he's exposed</p> <p>12 samples to five and six weeks' worth of exposure?</p> <p>13 A. I do know that.</p> <p>14 Q. Okay.</p> <p>15 A. I do know that.</p> <p>16 Q. Have you requested to look at</p> <p>17 those or test those or analyze those in any form?</p> <p>18 A. There was a discussion. I don't</p> <p>19 know if I said that I don't want to do it because I</p> <p>20 have my own and I believe it needs to be a year.</p> <p>21 Or maybe they used all their samples</p> <p>22 for SEM, and they didn't have anything left. But</p> <p>23 at that time the decision was to wait for my</p> <p>24 samples to become mature.</p> <p>25 Q. Okay. Did you submit this article</p> |
| Page 275 | Page 277 |
| <p>1 would hold stain?</p> <p>2 A. No. This paper was started, or</p> <p>3 most of the data was collected even before I</p> <p>4 learned about this simulation model. So it wasn't</p> <p>5 a part.</p> <p>6 Q. Did you ever discuss with Dr.</p> <p>7 Guelcher different ways to intentionally oxidize</p> <p>8 polypropylene?</p> <p>9 A. Later on. I mean, the manuscript</p> <p>10 was mainly written already and then we started</p> <p>11 discussing plans for the future. And then that's</p> <p>12 how I used the paper he suggested as a recipe for</p> <p>13 simulation.</p> <p>14 Q. Okay. So Dr. Guelcher suggested</p> <p>15 to you the paper that you used for the simulation?</p> <p>16 A. I think so.</p> <p>17 Q. Okay?</p> <p>18 A. Maybe I saw it before, but he</p> <p>19 pointed that, that's the recipe he was using as</p> <p>20 well.</p> <p>21 Q. Got it. Is Dr. Guelcher involved</p> <p>22 in your experimental work on the samples that</p> <p>23 you're now storing?</p> <p>24 A. No. I mean, I had my own samples.</p> <p>25 His contribution to this work is that I ask him</p> | <p>1 to multiple journals?</p> <p>2 A. There was submission to at least</p> <p>3 two journals and the answer was really quick, next</p> <p>4 day. They said no, it's not in our scope. And I</p> <p>5 was aiming at really high impact like Nature, so...</p> <p>6 Q. Nature turned it down?</p> <p>7 A. (Witness nods).</p> <p>8 Q. Okay.</p> <p>9 A. Are you surprised?</p> <p>10 Q. And so is the Journal of</p> <p>11 Biomedical Materials the only other journal that</p> <p>12 reviewed it?</p> <p>13 MR. ORENT: Objection.</p> <p>14 THE WITNESS: Yeah, this is my usual</p> <p>15 approach. For all my papers I start really high</p> <p>16 impact journal, hope for the best, and then go</p> <p>17 from there.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. Now, was there a peer-review</p> <p>20 process of this article?</p> <p>21 A. Yes. They ask for revisions, I</p> <p>22 did revisions, then we drafted it.</p> <p>23 Q. How many drafts did you have of</p> <p>24 Exhibit 6?</p> <p>25 A. We had one revision, one large</p> |

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| <p>1 revision. Part of the manuscript removed tables.</p> <p>2 MR. ORENT: I object to this whole line</p> <p>3 of questioning. It's outside of the scope of the</p> <p>4 expert testimony, and moreover I think there's a</p> <p>5 public policy interest in maintaining the integrity</p> <p>6 of the editorial board process of the journals.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Do you still have your first</p> <p>9 draft?</p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: I can't answer that.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. You can't?</p> <p>14 A. (Nods).</p> <p>15 Q. Why?</p> <p>16 A. It goes to the issues Mr. Orent</p> <p>17 just mentioned.</p> <p>18 Q. Okay. So have you maintained a</p> <p>19 file on the preparation, the data you gathered, the</p> <p>20 submission process and the peer-review process for</p> <p>21 Exhibit 6?</p> <p>22 A. Did I?</p> <p>23 Q. Yes.</p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: Yes, I did.</p> | <p>1 them are machine cut or laser cut?</p> <p>2 A. No.</p> <p>3 Q. You have four Prolift products; do</p> <p>4 you see that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. And then a number of hernia mesh</p> <p>7 cases, correct?</p> <p>8 A. That is correct.</p> <p>9 Q. Of the 69 slings that you</p> <p>10 analyzed, how many were medical-legal cases?</p> <p>11 A. The breakdown was about</p> <p>12 70 percent. I cannot tell you exact number. But</p> <p>13 roughly, it's for the whole set was 70 percent</p> <p>14 medical-legal and 30 percent hospital cases.</p> <p>15 And not necessarily St. Michael's.</p> <p>16 They were coming from different hospitals.</p> <p>17 Q. Okay. Is it fair to say if</p> <p>18 they're undetermined that they're not medical-legal</p> <p>19 cases?</p> <p>20 A. At least 70 percent were</p> <p>21 medical-legal.</p> <p>22 Q. I understand that, but I'm trying</p> <p>23 to break it down further to find out which ones</p> <p>24 were medical-legal and which ones were not.</p> <p>25 And you have 45 hernia cases that you</p> |
| Page 279 | Page 281 |
| <p>1 BY MR. THOMAS:</p> <p>2 Q. I just ask you to maintain that</p> <p>3 file and either I'll get it or I won't. Just don't</p> <p>4 do anything to it; that's all I ask.</p> <p>5 Just so I can short cut this. Is it</p> <p>6 fair to say you're not going to answer any more</p> <p>7 questions about the generation, drafting, peer</p> <p>8 review, submission and publication of the article?</p> <p>9 A. It was a standard process. There</p> <p>10 was nothing unusual about it.</p> <p>11 Q. But in terms of the details of it</p> <p>12 you're not going to answer any questions about</p> <p>13 that?</p> <p>14 A. No. I can tell that you there was</p> <p>15 nothing unusual.</p> <p>16 Q. I understand. If you'll turn to</p> <p>17 page 2, Table 1 is the sample and patient data?</p> <p>18 A. Yes.</p> <p>19 Q. And under "Slings", it says that</p> <p>20 you have 28 TVT or TVT-Os; do you see that?</p> <p>21 A. That is correct.</p> <p>22 Q. Do you know the breakdown between</p> <p>23 TVT and TVT-O?</p> <p>24 A. No.</p> <p>25 Q. Okay. Do you know whether any of</p> | <p>1 identify as undetermined. I'm making an assumption</p> <p>2 that because they're undetermined hernia cases that</p> <p>3 they're probably not medical-legal cases; is that a</p> <p>4 fair assumption?</p> <p>5 A. Some of them are medical-legal.</p> <p>6 Q. What percentage of the</p> <p>7 undetermined hernia cases were medical-legal; do</p> <p>8 you know?</p> <p>9 A. The undetermined are probably all</p> <p>10 non-medical-legal. I don't think medical-legal is</p> <p>11 undetermined.</p> <p>12 Q. That was my point?</p> <p>13 A. Yes.</p> <p>14 Q. So when we're making the</p> <p>15 calculation of the 70 percent, is it safe for us to</p> <p>16 exclude -- or strike that.</p> <p>17 Is it safe for us to include the 45</p> <p>18 undetermined hernia cases in the 30 percent of the</p> <p>19 non-medical-legal cases?</p> <p>20 A. Yes, we can do that right away.</p> <p>21 Those would be non-medical-legal cases.</p> <p>22 Q. Okay.</p> <p>23 A. There could be some potentially</p> <p>24 medical-legal cases when I receive a specimen but I</p> <p>25 have not received a history. They say, hold on to</p> |

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|---|--|
| <p>1 this -- may be medical-legal case later on.</p> <p>2 Q. Okay?</p> <p>3 A. So it's not hard number.</p> <p>4 Q. Right.</p> <p>5 A. But it's a ballpark.</p> <p>6 Q. For the Ethicon TVT, TVT-O of</p> <p>7 those 28 how many of them are medical-legal?</p> <p>8 A. At least 80 percent.</p> <p>9 Q. Perhaps more?</p> <p>10 A. Possibly more.</p> <p>11 Q. And included within the 28 Ethicon</p> <p>12 TVT and TVT-O are the cases that you received from</p> <p>13 Dr. Kreutzer, correct?</p> <p>14 A. Yes. Most of St. Michael's cases,</p> <p>15 when I had a record, were actually TVT. So I don't</p> <p>16 know for whatever reason most of those excised at</p> <p>17 St. Michael's were TVT.</p> <p>18 Q. Okay. And in addition, you had</p> <p>19 new TVT and TVT-O cases since Dr. Kreutzer, and</p> <p>20 those would be included in this article as well?</p> <p>21 A. Yes.</p> <p>22 Q. So, for example, the Edwards case</p> <p>23 would probably be in this?</p> <p>24 A. Yes, it would be in there. I</p> <p>25 received the Edwards case before I received</p> | <p>1 Q. Is it on the thumb drive?</p> <p>2 A. It's on the thumb drive. And you</p> <p>3 saw it before at various depositions.</p> <p>4 Q. Thank you. I don't want to redo</p> <p>5 that.</p> <p>6 And when you do the eyepiece micrometer</p> <p>7 and you measure, to what level can you measure?</p> <p>8 A. Initially, I had one micrometer.</p> <p>9 It was graded only to one micrometer. Now, I have</p> <p>10 little bit better so I can measure up to half a</p> <p>11 micrometer.</p> <p>12 Q. When you were doing this study,</p> <p>13 were you measuring at one micrometer?</p> <p>14 A. I was rounding to one micrometer;</p> <p>15 it was an older eyepiece.</p> <p>16 Q. So the data in the study, you're</p> <p>17 rounding your findings to the closest micrometer?</p> <p>18 A. Yes. To the full number.</p> <p>19 Q. Did you round up always?</p> <p>20 MR. ORENT: Objection.</p> <p>21 THE WITNESS: No, it depends. If it's</p> <p>22 less than a half of the next gradation, it would go</p> <p>23 to the lower, but that's the usual rule for --</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Okay, that's fine. And then when</p> |
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| <p>1 specimen from Dr. Kreutzer.</p> <p>2 Q. Okay. Interesting.</p> <p>3 On page 3 of this study, you talk about</p> <p>4 measuring the degradation layer's thickness?</p> <p>5 A. Yes.</p> <p>6 Q. And you say a set of 23</p> <p>7 mid-urethral slings was the largest uniform group</p> <p>8 that fulfilled your criteria. Is that the slings</p> <p>9 that you got from Dr. Kreutzer?</p> <p>10 A. Most of them came in that set of</p> <p>11 samples.</p> <p>12 Q. All right. Tell me how you</p> <p>13 physically measure the thickness of the stained</p> <p>14 layer with the eyepiece micrometer?</p> <p>15 A. I would find fibers which are cut</p> <p>16 as perpendicular as possible and measure bark</p> <p>17 thickness on at least two occasions.</p> <p>18 And then measure -- I try to find</p> <p>19 another fiber, measure again, and then take median</p> <p>20 number, the most frequent I'm getting.</p> <p>21 Q. Do you have the data that you</p> <p>22 collected on those measurements?</p> <p>23 A. Yes, I do.</p> <p>24 Q. Okay.</p> <p>25 A. I mean, you have it on the --</p> | <p>1 you had two together -- so you had a total of four</p> <p>2 measurements?</p> <p>3 A. I would aim at four measurements</p> <p>4 at least.</p> <p>5 Q. And each one of those would go</p> <p>6 through some rounding process?</p> <p>7 A. Yeah, I mean, the accuracy of</p> <p>8 measurement was within half a micrometer plus or</p> <p>9 minus.</p> <p>10 Q. Okay. Now --</p> <p>11 A. But it would be random, up and</p> <p>12 down, up and down, so they would constantly change.</p> <p>13 Q. Now, in some places in images we</p> <p>14 looked at today, we didn't find any bark, correct?</p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: This is not correct. We</p> <p>17 could not see it in the images. I can tell you</p> <p>18 that in some specimens I did not see bark.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. How do you report that?</p> <p>21 A. I report that I don't see it. I</p> <p>22 have cases when I reported that I don't see a bark.</p> <p>23 Q. And you reported here that you had</p> <p>24 two specimens where the degradation layer was not</p> <p>25 visible where a hernia mesh and a sling were</p> |

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|--|---|
| <p>1 removed at three and ten months.</p> <p>2 Are those the only two times you</p> <p>3 haven't been able to see a bark?</p> <p>4 A. At that time, the only two. Since</p> <p>5 then I've seen a couple of more cases where I</p> <p>6 couldn't identify bark.</p> <p>7 Q. Any of those medical-legal cases?</p> <p>8 A. No, I think it was all hernia</p> <p>9 meshes, not medical-legal cases.</p> <p>10 Q. Do you have those slides</p> <p>11 available?</p> <p>12 MR. ORENT: Objection.</p> <p>13 THE WITNESS: Yes, I do, but they are</p> <p>14 of patients.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. You can't produce those to me if I</p> <p>17 asked you for them?</p> <p>18 A. I can't produce them.</p> <p>19 Q. Did the slides where there was no</p> <p>20 degradation bark, if you will, present contain</p> <p>21 inflammation?</p> <p>22 A. Yes, they did.</p> <p>23 Q. Were they removed because of pain?</p> <p>24 A. Yes. I think one of them was</p> <p>25 removed for erosion with pain. The other one, the</p> | <p>1 part of research project.</p> <p>2 Q. Well, have you produced that to us</p> <p>3 before?</p> <p>4 A. I don't know.</p> <p>5 Q. Okay. But just to make sure I got</p> <p>6 a clean answer. In all the work that you've done</p> <p>7 on all the Ethicon meshes, the only Ethicon mesh</p> <p>8 that you've analyzed by transmission electron</p> <p>9 microscopy is a mesh of a St. Michael's patient</p> <p>10 that's either a TVT or a Prolift, you don't know</p> <p>11 which?</p> <p>12 A. Now I'm not sure if it was St.</p> <p>13 Michael's or it was a medical-legal case. I don't</p> <p>14 remember now.</p> <p>15 Q. Okay?</p> <p>16 A. I would have to check, but if it</p> <p>17 was, it was the only case. I could do only one</p> <p>18 case of Ethicon mesh by transmission electron</p> <p>19 microscopy.</p> <p>20 Q. And why have you not conducted</p> <p>21 transmission electron microscopy on other meshes?</p> <p>22 A. There was no need. It is a really</p> <p>23 cumbersome, difficult and --</p> <p>24 Q. Does St. Michael's have that kind</p> <p>25 of equipment?</p> |
| Page 287 | Page 289 |
| <p>1 hernia mesh, was removed just for pain.</p> <p>2 Q. On page 6 of the study, you</p> <p>3 describe that you use transmission electron</p> <p>4 microscopy --</p> <p>5 A. That's correct.</p> <p>6 Q. -- to study the ultra structural</p> <p>7 organization of the degraded layer in</p> <p>8 cross-sections?</p> <p>9 A. That's correct.</p> <p>10 Q. Did you use the TEM to study any</p> <p>11 TVT device?</p> <p>12 A. One. It was one Ethicon device,</p> <p>13 TVT or Prolift, I don't remember. I think it was a</p> <p>14 TVT.</p> <p>15 Q. Have you produced that work to us</p> <p>16 before?</p> <p>17 A. It's a St. Michael's Hospital</p> <p>18 patient.</p> <p>19 Q. Okay. So, is it fair to</p> <p>20 understand that the only transmission electron</p> <p>21 microscopy analysis that you've done on an Ethicon</p> <p>22 mesh is the St. Michael's patient that you can't</p> <p>23 produce to us?</p> <p>24 A. Well, it was a part of research.</p> <p>25 So if it was included in images, it was included as</p> | <p>1 A. Yes, we do. Otherwise, I wouldn't</p> <p>2 be able to do it. It's really expensive to do it</p> <p>3 somewhere outside.</p> <p>4 Q. Did you have to pay St. Michael's</p> <p>5 to do this?</p> <p>6 A. No, it's just part of our academic</p> <p>7 work.</p> <p>8 Q. Are you able to do this yourself</p> <p>9 or does somebody have to do it for you?</p> <p>10 A. I'm trained to do transmission</p> <p>11 electron microscopy. I mean, technicians prepare</p> <p>12 slides. It's usual, the same as for histology.</p> <p>13 But I do examination myself.</p> <p>14 Most of the transmission electron</p> <p>15 microscopy samples are with hernia meshes.</p> <p>16 Q. Page 10 there is a discussion of</p> <p>17 the clinical significance of polypropylene</p> <p>18 degradation?</p> <p>19 MR. ORENT: Are we going back to the</p> <p>20 report or saying on the study?</p> <p>21 MR. THOMAS: I'm on the study, sorry.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Page 10 on Exhibit 6, "Clinical</p> <p>25 Significance of Polypropylene Degradation".</p> |

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| <p style="text-align: right;">Page 290</p> <p>1 Who drafted this section?</p> <p>2 A. Mostly me, partially my coauthors.</p> <p>3 Q. Dr. Bendavid?</p> <p>4 A. Yes. And well, mostly Dr.</p> <p>5 Bendavid. I mean, I drafted most of it, but I was</p> <p>6 getting some corrections or changes, and the</p> <p>7 changes were coming mostly from Dr. Bendavid.</p> <p>8 Q. Exhibits 5 and 6, you stand by the</p> <p>9 findings stated in each of those articles?</p> <p>10 A. Yes, I am.</p> <p>11 Q. Do you have depositions scheduled</p> <p>12 in the next month?</p> <p>13 A. I'm not sure if I can disclose</p> <p>14 that.</p> <p>15 Q. Do you have trial responsibilities</p> <p>16 in the next month?</p> <p>17 A. Pardon?</p> <p>18 Q. Do you have any trial</p> <p>19 responsibilities in the next month?</p> <p>20 A. No, I don't think so.</p> <p>21 Q. Your next trial is a December</p> <p>22 trial with Ethicon?</p> <p>23 A. I'm not sure if I can disclose</p> <p>24 that either.</p> <p>25 Q. Are you choosing not to?</p> | <p style="text-align: right;">Page 292</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. Do you have any set dates for any</p> <p>3 trials between now and the Ethicon trial?</p> <p>4 A. No. Again, nothing set firmly.</p> <p>5 Q. Okay.</p> <p>6 MR. ORENT: Just a sec. In addition to</p> <p>7 that, I think in the Cantrell matter I've been</p> <p>8 working with Kelly Crawford to schedule, I would</p> <p>9 imagine that would be within the next month.</p> <p>10 That's an Ethicon case, obviously.</p> <p>11 MR. THOMAS: Yes, I know about that.</p> <p>12 Hang on. Getting close to the end.</p> <p>13 -- OFF THE RECORD DISCUSSION --</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Doctor, I'm told that the</p> <p>16 information supplied to us concerning the eyepiece</p> <p>17 micrometer measurements of the bark layers is</p> <p>18 expressed in a single value as opposed to the four</p> <p>19 individual measurements?</p> <p>20 A. No, it's a median, I told you</p> <p>21 that, then I pick median value out of four.</p> <p>22 Q. Okay.</p> <p>23 A. It is described in the paper. So</p> <p>24 the volume which goes for analysis is a median one,</p> <p>25 which is more frequent.</p> |
| <p style="text-align: right;">Page 291</p> <p>1 A. There might be more and earlier, I</p> <p>2 don't want to disclose that. I'm not sure if I</p> <p>3 can, if I legally can disclose it.</p> <p>4 I mean, if it's not for Ethicon cases.</p> <p>5 For Ethicon I would disclose, but if it's not then</p> <p>6 I cannot disclose.</p> <p>7 MR. THOMAS: Counsel, there's no legal</p> <p>8 prohibition for him saying it?</p> <p>9 MR. ORENT: You can answer.</p> <p>10 THE WITNESS: They said that --</p> <p>11 MR. ORENT: Wait, hold on. They said</p> <p>12 is not an answer. So any communications that</p> <p>13 you've had are covered by a privilege. So what</p> <p>14 he's asking specifically are, if anything is firm</p> <p>15 in terms of a date that you know of, so --</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. For depositions or trial?</p> <p>18 MR. ORENT: For depositions or trial,</p> <p>19 not any communications about we might do this or</p> <p>20 might do that. But anything firm that you know you</p> <p>21 have a date set for.</p> <p>22 THE WITNESS: Then everything is</p> <p>23 changing. I have a set date one deposition. But</p> <p>24 the rest is still in the air.</p> <p>25</p> | <p style="text-align: right;">Page 293</p> <p>1 Q. Do you have the four measurements</p> <p>2 that you made or did you just pick the -- do you</p> <p>3 have that as a part of your data set?</p> <p>4 A. I just measure them and right</p> <p>5 there I know how frequent is this measurement or</p> <p>6 that. So I don't have to put in the paper.</p> <p>7 Q. Did you write down or keep a copy</p> <p>8 of the four individual measurements that you made</p> <p>9 of the --</p> <p>10 A. No, no. The methodology is check</p> <p>11 four spots. I see three, four, four, four, then</p> <p>12 four is the winner, so then four goes in the</p> <p>13 record.</p> <p>14 Q. Did you produce your bills today</p> <p>15 for the time that you spent in this case?</p> <p>16 A. In this case?</p> <p>17 Q. In this case?</p> <p>18 A. Oh, in this. I had billing done</p> <p>19 for the -- for the report, it's in the folder.</p> <p>20 Q. Do you recall how much time and</p> <p>21 money you've spent on preparing the report in this</p> <p>22 case, Exhibit 3 and 4?</p> <p>23 A. No, I don't.</p> <p>24 Q. The invoice that you produced to</p> <p>25 us on a thumb drive suggests that you have a</p> |

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|---|--|
| <p>1 balance, professional services August 14th,</p> <p>2 August 24th for a total of \$8,550 --</p> <p>3 A. Sounds right.</p> <p>4 Q. -- is that right?</p> <p>5 Doctor, I don't see -- I see general</p> <p>6 part text revision; what does that mean?</p> <p>7 A. Revision of the general part.</p> <p>8 Q. General party report?</p> <p>9 A. Yes.</p> <p>10 Q. This report is the first time that</p> <p>11 you reviewed any Ethicon documents or Ethicon</p> <p>12 depositions, true?</p> <p>13 A. No, there was another case.</p> <p>14 Q. I didn't see it in any of your</p> <p>15 reports before where you reviewed Ethicon</p> <p>16 depositions and Ethicon documents?</p> <p>17 MR. ORENT: One moment.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. The only other case it could be</p> <p>20 would be the Bellew case?</p> <p>21 MR. ORENT: The doctor has not</p> <p>22 testified previously about these issues. I don't</p> <p>23 know whether or not there has been another report</p> <p>24 on another matter disclosed.</p> <p>25 It may very well be that there is</p> | <p>1 MR. ORENT: Why don't we take two</p> <p>2 minutes. I'll going to have probably about ten</p> <p>3 minutes worth of questions.</p> <p>4 -- RECESS TAKEN AT 4:52 --</p> <p>5 -- UPON RESUMING AT 4:55 --</p> <p>6 CROSS-EXAMINATION BY MR. ORENT:</p> <p>7 Q. Good afternoon, Doctor.</p> <p>8 A. Good afternoon.</p> <p>9 Q. Earlier today you were asked a</p> <p>10 number of questions about each of the</p> <p>11 photomicrographs that we looked at, and one of the</p> <p>12 predicate questions that you were asked for each</p> <p>13 one was whether or not it was a TVT or a TVT-O; do</p> <p>14 you recall being asked that series of questions?</p> <p>15 A. Yes, I do.</p> <p>16 Q. For purposes of your work does it</p> <p>17 make any difference whether or not the product is</p> <p>18 the TVT or TVT-O in terms of your findings as</p> <p>19 reported here?</p> <p>20 A. No, it's the same sling, the same</p> <p>21 mesh. The only difference is how it's placed and</p> <p>22 the other components which come in the kit.</p> <p>23 Q. So if I understand your testimony,</p> <p>24 is it your testimony that the TVT and the TVT-O --</p> <p>25 the actual mesh device is the exact same?</p> |
| Page 295 | Page 297 |
| <p>1 something that's still work product and not been</p> <p>2 disclosed. So I don't want to get into the details</p> <p>3 of that other potential matter.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Let me just ask it this way: The</p> <p>6 bills that you've submitted to counsel in this</p> <p>7 matter do not reflect any charges for time that</p> <p>8 you've spent reviewing Ethicon documents or</p> <p>9 depositions, correct?</p> <p>10 A. Partially, they do. I reviewed</p> <p>11 some of that again; it's been drafted earlier.</p> <p>12 MR. ORENT: Counsel, just to speed this</p> <p>13 area up to the extent that it's not clear on the</p> <p>14 bills, I think what we can do is we can supplement</p> <p>15 by letter.</p> <p>16 MR. THOMAS: That would be fine. I'm</p> <p>17 not interested in getting anybody. I just want --</p> <p>18 MR. ORENT: I think what we'll do is we</p> <p>19 can figure out the amount of time.</p> <p>20 MR. THOMAS: I just want to make sure</p> <p>21 you get paid for your time. You have to send your</p> <p>22 bills and get paid.</p> <p>23 Okay, that's all the questions I have,</p> <p>24 Doctor. Thank you.</p> <p>25 THE WITNESS: Thank you.</p> | <p>1 A. Exactly the same.</p> <p>2 Q. Okay. And so in terms of the</p> <p>3 pathological findings that you make, as reported in</p> <p>4 your report and your supplement, is there a -- is</p> <p>5 there any reason for making a distinction between</p> <p>6 the two devices?</p> <p>7 MR. THOMAS: Object to the form of the</p> <p>8 question.</p> <p>9 THE WITNESS: No. The only difference</p> <p>10 is there can be more frequent occurrences of</p> <p>11 striated muscle in the TVT-O samples than in TVT,</p> <p>12 but it can be seen in both.</p> <p>13 BY MR. ORENT:</p> <p>14 Q. And is that because of the</p> <p>15 implantation route?</p> <p>16 A. That's correct.</p> <p>17 Q. And both devices are made of</p> <p>18 Prolene mesh; is that correct?</p> <p>19 A. That is correct.</p> <p>20 Q. Now every one of the</p> <p>21 photomicrographs that appear in Exhibits 1 and 2 to</p> <p>22 today's deposition, that is your report and</p> <p>23 supplemental report, did every one of those</p> <p>24 photomicrographs appear either from prior expert</p> <p>25 reports in Ethicon litigation, in the specific</p> |

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| <p>1 pathology of the consolidated plaintiffs, or in 2 peer-reviewed medical literature written by you? 3 A. That's correct. These are the 4 three sources. 5 Q. And you've been asked questions 6 today about identifying various -- what you called 7 additional TVT cases in your report; do you recall 8 those questions? 9 A. Yes, I do. 10 Q. Did you produce photomicrographs 11 of the additional TVT cases in the course of other 12 reports you've provided in TVT cases? 13 A. Yes, I did. 14 Q. Now, with regard to the opinions 15 that you express in your expert report in this 16 case, and your supplement, do you use the same 17 methodology that you have previously used when you 18 testified in the western district -- excuse me, in 19 the southern district of West Virginia? 20 A. Yes, exactly the same methodology. 21 Q. And is your -- the materials and 22 your methodology that you utilized in this report 23 the same methodology that you've used in other 24 courts where you have been allowed to testify at 25 trial?</p> | <p>1 device; is that correct? 2 MR. THOMAS: Object to form. 3 THE WITNESS: That is correct. 4 BY MR. ORENT: 5 Q. And why is it that you don't list 6 a sample size or rate of error in your report? 7 A. It's not the purpose. I'm not 8 analyzing statistically frequency or rate of 9 occurrence. I showed the changes which can occur. 10 It's binary assessment; either it can occur or 11 cannot occur. It can occur in one case, it can 12 occur in 100 percent of cases, but it can happen. 13 For a specific patient it either occurs or it 14 doesn't. 15 Q. In order to show that something 16 can occur, in terms of a failure mode, is there a 17 sample size, a minimum sample size that you have 18 need to show that a failure rate or failure mode 19 can occur? 20 MR. THOMAS: Object to form. 21 THE WITNESS: One case is enough. If 22 it can occur in one case, it can occur again. 23 BY MR. ORENT: 24 Q. And these concepts of sample size 25 with one being enough to prove capability, is that</p> |
| Page 299 | Page 301 |
| <p>1 A. That's correct. 2 Q. Did you use any different 3 techniques in this report? 4 A. No. 5 Q. Okay. Now, the opinions that you 6 testified to in this report, and in the supplement, 7 are they identical to the opinions that you've 8 previously provided in trial in matters before the 9 southern district of West Virginia? 10 A. Yes. 11 MR. THOMAS: Object to form. 12 THE WITNESS: That is correct. The 13 same opinions. 14 BY MR. ORENT: 15 Q. Are they, the opinions that you 16 express in your expert report and in the 17 supplement, are they also identical to opinions 18 that you have provided in other courts during 19 trials throughout the country? 20 MR. THOMAS: Object to form. 21 THE WITNESS: That is correct. 22 BY MR. ORENT: 23 Q. And throughout the course of your 24 report you provide just a few examples of a variety 25 of failure modes associated with the TVT and TVT-O</p> | <p>1 something that's generally accepted in the medical 2 community, in the scientific community? 3 MR. THOMAS: Object to form. 4 THE WITNESS: Yes. If you answer the 5 question if it can occur, one case is enough. 6 BY MR. ORENT: 7 Q. Same thing with a binary 8 observation; it either occurs or doesn't occur. 9 There's no rate of error associated with that; is 10 that correct? 11 MR. THOMAS: Object to the form of the 12 question. 13 THE WITNESS: It's either there or it's 14 not. It's either zero occurrence or 100 percent. 15 BY MR. ORENT: 16 Q. When you talk about using large 17 enough sample sizes and large enough rates of 18 error, is that only used when you actually try and 19 extrapolate from a data set to an individual? 20 MR. THOMAS: Object to the form of the 21 question. 22 THE WITNESS: That's used to predict 23 specific rates of specific occurrence, and that's 24 used in relation to a cohort of patients and 25 devices. And it's a different question.</p> |

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|--|---|
| <p>1 BY MR. ORENT:</p> <p>2 Q. Okay. And in terms of the</p> <p>3 opinions that you provided here in your expert</p> <p>4 report, do you hold each of those opinions to a</p> <p>5 reasonable degree of medical and professional</p> <p>6 certainty?</p> <p>7 A. Yes, I do.</p> <p>8 Q. And with regard to the various</p> <p>9 staining techniques that you've utilized, are each</p> <p>10 one of those staining techniques peer-reviewed in</p> <p>11 their own right?</p> <p>12 MR. THOMAS: Object to the form of the</p> <p>13 question.</p> <p>14 THE WITNESS: That is correct, yes.</p> <p>15 BY MR. ORENT:</p> <p>16 Q. Has H&E been utilized as a stain</p> <p>17 and been peer-reviewed as a proper way of looking</p> <p>18 at tissue for a significant period of time?</p> <p>19 A. Over 100 years, or over the course</p> <p>20 of 100 years.</p> <p>21 Q. How about myeloperoxidase, has</p> <p>22 that been peer-reviewed as use for staining?</p> <p>23 MR. THOMAS: Object to the form of the</p> <p>24 question.</p> <p>25 THE WITNESS: We have several decades</p> | <p>1 question.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. ORENT:</p> <p>4 Q. Now, with regard to the work that</p> <p>5 you've done here, none of these opinions are new;</p> <p>6 is that right?</p> <p>7 MR. THOMAS: Object to the form of the</p> <p>8 question.</p> <p>9 THE WITNESS: That is correct.</p> <p>10 BY MR. ORENT:</p> <p>11 Q. And in terms of the material that</p> <p>12 you've produced on disk. Having provided to</p> <p>13 counsel today, did you produce all non-confidential</p> <p>14 materials that you could provide?</p> <p>15 A. Yes. I selected that I could</p> <p>16 safely release.</p> <p>17 Q. You were also asked a number of</p> <p>18 questions about the peer review and peer-review</p> <p>19 process; do you recall those questions?</p> <p>20 A. Yes, I do.</p> <p>21 Q. As an academic, do you have</p> <p>22 concerns about maintaining the integrity of the</p> <p>23 peer-review process?</p> <p>24 A. Could you repeat the question.</p> <p>25 Q. Sure. As an academic, as an</p> |
| Page 303 | Page 305 |
| <p>1 of use.</p> <p>2 BY MR. ORENT:</p> <p>3 Q. And how about S100?</p> <p>4 MR. THOMAS: Object to the form of the</p> <p>5 question.</p> <p>6 THE WITNESS: Same thing. It's been</p> <p>7 used since late '70s, early '80s.</p> <p>8 BY MR. ORENT:</p> <p>9 Q. What about the use of polarizing</p> <p>10 light, is that something that's peer-reviewed and</p> <p>11 accepted in the identification of crystalline</p> <p>12 substances?</p> <p>13 A. It's been described for histology</p> <p>14 use from 1920s, and even I saw it's been used in</p> <p>15 Ethicon studies as well. Ethicon scientists were</p> <p>16 using polarized light as well. Well, let me</p> <p>17 rephrase that. Who came to the same conclusions I</p> <p>18 came.</p> <p>19 Q. And with regard to the medical</p> <p>20 peer-reviewed literature on mesh and mesh</p> <p>21 complications, in fact, there's a group out of the</p> <p>22 University of Michigan that published utilizing</p> <p>23 some of the same techniques that you've described</p> <p>24 in your report; is that correct?</p> <p>25 MR. THOMAS: Object to the form of the</p> | <p>1 author and a researcher, are there important</p> <p>2 reasons why the confidentiality of the</p> <p>3 peer-review process needs to be maintained?</p> <p>4 A. Yes. I mean, especially when</p> <p>5 there is an involvement of a manufacturer, because</p> <p>6 I mean, this is major concern.</p> <p>7 Most publications -- journals, they</p> <p>8 require, the first thing they need to have</p> <p>9 submitted, has it been funded by industry, by</p> <p>10 manufacturers. So it's a major concern to try to</p> <p>11 be independent from manufacturers.</p> <p>12 MR. ORENT: All right, Doctor, thank</p> <p>13 you very much. I have no further questions.</p> <p>14 MR. THOMAS: Thank you, Doctor, for</p> <p>15 your time.</p> <p>16</p> <p>17</p> <p>18 -- Whereupon the deposition concluded at 5:05 p.m.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |

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| 1 REPORTER'S CERTIFICATE | 1 INSTRUCTIONS TO WITNESS |
| 2 | 2 |
| 3 | 3 Read your deposition over carefully. |
| 4 I, JUDITH M. CAPUTO, RPR, CSR, CRR, | 4 It is your right to read your deposition and make |
| 5 Registered Professional Reporter, certify; | 5 changes in form or substance. You should assign a |
| 6 That the foregoing proceedings were | 6 reason in the appropriate column on the erratum |
| 7 taken before me at the time and place therein set | 7 sheet for any change made. |
| 8 forth, at which time the witness was put under oath | 8 After making any changes in form or |
| 9 by me; | 9 substance, and which have been noted on the |
| 10 That the testimony of the witness and | 10 following erratum sheet, along with the reason for |
| 11 all objections made at the time of the examination | 11 any change, sign your name on the erratum sheet and |
| 12 were recorded stenographically by me and were | 12 date it. |
| 13 thereafter transcribed; | 13 Then sign your deposition at the end of |
| 14 That the foregoing is a true and | 14 Your testimony in the space provided. You are |
| 15 correct transcript of my shorthand notes so taken. | 15 signing it subject to the changes you have made in |
| 16 | 16 the erratum sheet, which will be attached to the |
| 17 | 17 deposition before filing. You must sign it in |
| 18 | 18 front of a witness. The witness need not be a |
| 19 Dated this 14th day of September, 2015. | 19 notary public. Any competent adult may witness |
| 20 | 20 your signature. |
| 21 | 21 Return the original erratum sheet |
| 22 | 22 promptly. Court rules require filing within 30 |
| 23 | 23 days after you receive the deposition. |
| 24 PER: JUDITH CAPUTO, RPR, CSR, CRR | 24 |
| 25 | 25 |
| Page 307 | Page 309 |
| 1 CERTIFICATE OF REPORTER | 1 ** ERRATA SHEET ** |
| 2 CANADA) | 2 |
| 3 PROVINCE OF ONTARIO) | 3 NAME OF CASE: TERRESKI MULLINS, ET AL. V. |
| 4 | 4 ETHICON, INC., ET AL. |
| 5 I, Judith M. Caputo, the officer before whom the | 5 DATE OF DEPOSITION: SEPTEMBER 14th, 2015 |
| 6 foregoing deposition was taken, do hereby certify | 6 NAME OF WITNESS: VLADIMIR IAKOVLEV |
| 7 that the witness whose testimony appears in the | 7 |
| 8 foregoing deposition was duly sworn by me; that the | 8 |
| 9 testimony of said witness was taken by me in | 9 PAGE LINE FROM TO |
| 10 shorthand, using Computer Aided Realtime, to the | 10 |
| 11 best of my ability and thereafter reduced to | 11 |
| 12 written format under my direction; that I am | 12 |
| 13 neither counsel for, related to, nor employed by | 13 |
| 14 any of the parties to the action in which the | 14 |
| 15 deposition was taken, and further that I am not | 15 |
| 16 related or any employee of any attorney or counsel | 16 |
| 17 employed by the parties thereto, nor financially or | 17 |
| 18 otherwise interested in the outcome of the action. | 18 |
| 19 | 19 |
| 20 | 20 |
| 21 | 21 |
| 22 Judith M. Caputo, RPR, CSR, CRR | 22 |
| 23 | 23 |
| 24 Commissioner for taking | 24 |
| 25 Oaths in the Province of Ontario | 25 VLADIMIR IAKOVLEV |

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| <p style="text-align: right;">Page 310</p> <p>1 PROVINCE OF ONTARIO) 2 TORONTO REGION) 3 4 5 I, the undersigned, declare under 6 penalty of perjury that I have read the foregoing 7 transcript, and I have made any corrections, 8 additions or deletions that I was desirous of 9 making; 10 That the foregoing is a true and 11 correct transcript of my testimony contained 12 therein. 13 14 _____ 15 VLADIMIR IAKOVLEV, M.D. 16 17 18 Subscribed and sworn to before me this ____ 19 Day of _____, 2015 at 20 _____, 21 (City) (Province) 22 23 _____ 24 (Notary Public) 25 My Commission Expires: _____</p> | |
| | |